A Dissertation On

THE EFFECT OF AURICULOPUNCTURE IN PATIENTS WITH PERIARTHRITIS SHOULDER- A PROSPECTIVE RANDOMIZED CONTROL STUDY

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LIST OF ABBREVIATIONS

AA	Auricular Acupuncture	**MMP**	Matrix Metalloproteinase
ABVN	Auricular branches of Vagus Nerve	**IGF**	Insulin-like growth factor
AC	Adhesive Capsulitis	**NSAIDs**	Non-Steroidal Anti-Inflammatory Drugs
ACR	AuriculoCardiac Reflex	**PDGF**	Platelet Derived Growth Factor
aROM	Active Range Of Motion	***p***	Probability
ASIC	Acid Sensing Ion Channel	**PAS**	Periarthritis of Shoulder
AT	Auriculotherapy	**ROM**	Range of Motion
BSAA	Brain Stem AuricularAcupoint	**SD**	Standard Deviation
COX	Cyclooxygenase	**TIMP**	Tissue Inhibitor of Metalloproteinase
CN	Cranial Nerve	**SPSS**	Statistical Package for the Social Sciences
FGF	Fibroblast Growth Factor	**VAS**	Visual Analog Scale
ILs	Interleukins	**TCM**	Traditional Chinese medicine
MRI	Magnetic Resonance Imaging	**SPADI**	Shoulder Pain and its Disability Index
NSAIDs	Non Steroidal Antiinflammatory Drugs	**TAA**	Thumb auricular acupoint
FS	Frozen Shoulder	**TNF**	Tumor Necrosis Factor
NTS	Nucleus of the Solitary tract	**TGF**	Tumor Growth Factor
HRV	Heart Rate Variability	**TKR**	Total knee Replacement

ABSTRACT

Background: Frozen shoulder is also referred to as adhesive capsulitis, painful stiff shoulder, and periarthritis**.**The lifetime prevalence of frozen shoulder is estimated to be 2 to 5 percent of the general population. Patients with diabetes mellitus are at greater risk of developing frozen shoulder, with a prevalence of 10 to 20 percent. Auricular acupuncture (AA) is called the treatment of physical and psychosomatic dysfunctions by stimulating the ear surface exclusively. Previous studies have reported that AA can releive pain improve Range of motion. This study is designed to asses the effects of AA on PAS patients.

Methods : Sixty subjects aged between 40 to 60 years presents with symptoms of PAS were randomly assigned into(control group n=30) and Auricular acupuncture (Experimental group n=30). Both groups were assessed at the baseline and at the end of 12 sessions in 14 days. Shoulder pain were scored by SPADI (Shoulder pain and disability index) pain and ROM was measured in terms of shoulder abduction, flexion and external rotation. The sterile acupuncture needles were inserted in the ear of the subjects at specific points (such as Jerome point, thalamus point, Shenmen point,shoulder joint point,shoulder point) for 20 minutes of duration.

Results : SPADI score and ROM were improved in both the groups. But AA group shows highly significant results clinically as well as statistically in pain

index (0.00), disability index (*0.002*), total SPADI score (0.001), ROM in shoulder flexion (0.002), abduction (0.001) and in external rotation (0.00).

Conlusion : AA showed greater effect in ROM. Although this study shows that an AA is highly recommended for PAS, future research with a large cohort study with long monitoring is needed to validate these results.

Keywords : Periarthritis of shoulder, Auriculotherapy, Shoulder pain, SPADI, Range of motion.

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1.0 INTRODUCTION

Adhesive capsulitis (AC) or Periarthritis of shoulder (PAS) is a common painful ailment of shoulder. It is commonly called as frozen shoulder. The actual definition given by American Shoulder and Elbow Surgeons consensus is as follows “functional restriction of both active and passive shoulder motion for which radiographs of the glenohumeral joint are essentially unremarkable except for the possible presence of osteopenia or calcific tendonitis”(1). It is a debilitating pathological condition of the glenohumeral joint, characterised by stiffness, pain and dysfunction(2). 2-5% of the population is affected by this condition. Most common in women and people aged between 40 and 60 years of age (3).

Diagnosing PAS can be contentious in the very early stage. Diagnosis is based on clinical findings (4).Onset of shoulder pain is the earliest symptom followed by loss of motion, specifically patients first report about external rotation movement restriction(5). Contraction of coracohumeral ligament leads to restriction in external rotation (6). X-ray images are useful in eliminating the other reasons for shoulder pain and stiffness. Suggestive features of PAS includes capsular thickening, and loss of the inferior axillary pouch and joint volume, these can be detected using ultrasound, magnetic resonance imaging (MRI) and magnetic resonance arthrography(7). PAS patients blood test profiles are generally normal, possibility of elevated cholesterol, triglycerides and C-reactive protein might be seen in early stages(4). The characteristic pathological features of PAS are inflamed

glenohumeral and subacromial synovium, and thickening and contracture of joint capsule, particularly the rotator interval and coracohumeral ligament (1).

Auricle means the visible part of the ear. Ear is a micro system, which reflects the entire body, represented on the auricle. Treating physical and psychosomatic dysfunctions by exclusively stimulating the surface of the ear is called auricular acupuncture (AA). Ear stimulation involves the triggering of neurological reflex, neurotransmitters, cytokines, the immune system, and inflammation.

In Traditional Chinese Medicine (TCM), the ear is directly or in directly connected with 12 meridians, and stimulating the ear can restore the balance between Qi and blood (6).

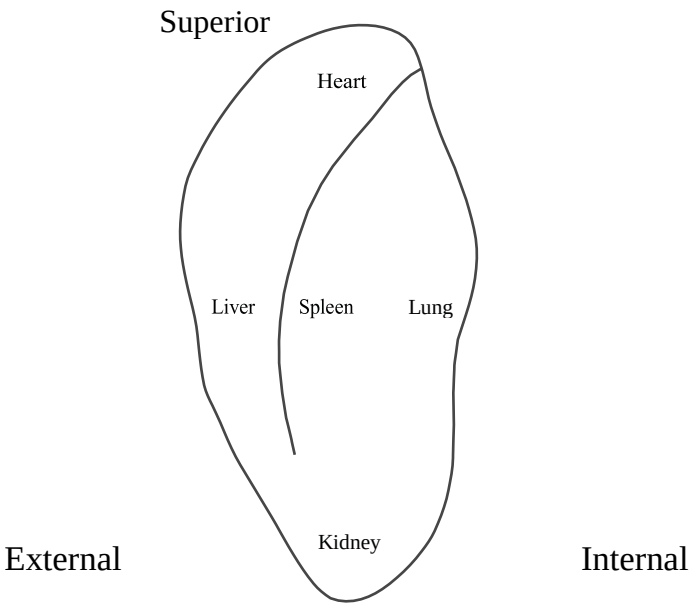
1.1 Anatomy of the Auricle.

The basic terminology regarding the auricle concerns the prominent parts (i.e., the helix, antihelix [including the superior and inferior crus], and the tragus and antitragus); the concave parts (i.e., the scaphoid fossa, triangular fossa, and the superior and inferior concha); and a flat part (i.e., the lobe; Figure 2) . The motor area includes the motor branch of the facial nerve (CN VII), which is responsible for the control of outer ear muscles. The sensory area is composed of auricular branches of the vagus nerve (ABVN), the auriculotemporal nerve (a branch of CN V), the facial nerve, the glossopharyngeal nerve, the lesser occipital nerve, and the greater auricle nerve (6).

1.2 Theory of Auricular Acupuncture

Somatotopic Arrangement (Homuncular Theory). Nogier had devised the map of an inverted foetus by noting its resemblance to the ear, and this map is the most widely used as reference for diagnosing and treating auricular diseases (Figure 3). The general arrangement is that the earlobe targets the head and brain, the antihelix represents the spine, the scaphoid fossa refers to the upper extremities the superior and inferior crus target the lower extremities, and the concha represents the internal organs, but numerous differences still exist between the Europe and Chinese system (8). Nogier believed that the relationship between AA and the areas of the body is due to the vagus nerve autonomic nervous system (ANS) (9).

Fig 1.The five viscera distribution of ear in Traditional Chinese Medicine .



1.3 Embryological Regions.

Embryological organization is similar to somatotopic organization. The earlobe and tragus correspond to the ectoderm, the concha corresponds to the endoderm, and the remaining portion of the ear corresponds to the mesoderm. If an organ (e.g., the lungs) corresponds to the endoderm, we can use the concha to treat or diagnose the condition (10). The distribution of embryological regions is based on the lower portion of the ear representing the head and the upper portion representing the foot (9).

1.4 Meridian Theory.

According to meridian theory, the ear is connected directly or indirectly to 12 meridians. The miraculous pivot of Huang Di Nei Jing indicated that any channel and meridian converge in the ear (11). The application of AA in TCM is based on yin-yang theory and five-element theory, but most auricular treatments involve the acupoints of the four limbs and the visceral and endocrine related areas innervated by vagus nerve (12).

1.5 Mechanisms of Action

1.5.1 Connection between the Auricle and Autonomic Nervous System.

In 1832, Friedrich Arnold, a German professor of anatomy, found that stimulating the external ear canal can induce a cough similar to the cough reflex induced by the vagal nerve. This reflex is called “Arnold’s Reflex” and regards the ABVN as it is an afferent nerve . Because ABVN stimulation can

induce a response similar to that of the vagal nerve, the ABVN may have a relationship of the auricle and ANS (6).

The ABVN delivers a fibre into the nucleus of the solitary tract (NTS). Nomura and Mizuno (1984) applied horseradish peroxide to the end of the ABVN in cats and found that the labelled nerve fibres of the ABVN surround the NTS . The inputs of the NTS include fibres from the facial nerve (CN VII), the glossopharyngeal nerve (CN IX), the vagus nerve (CN X), and afferent nerves in the internal organs. By contrast, the NTS outputs include reticular formation, parasympathetic preganglionic neurons to the viscera, the paraventricular nucleus of the hypothalamus, the thalamus (visceromotor centre), and amygdala(6).

Anatomical structure of ear

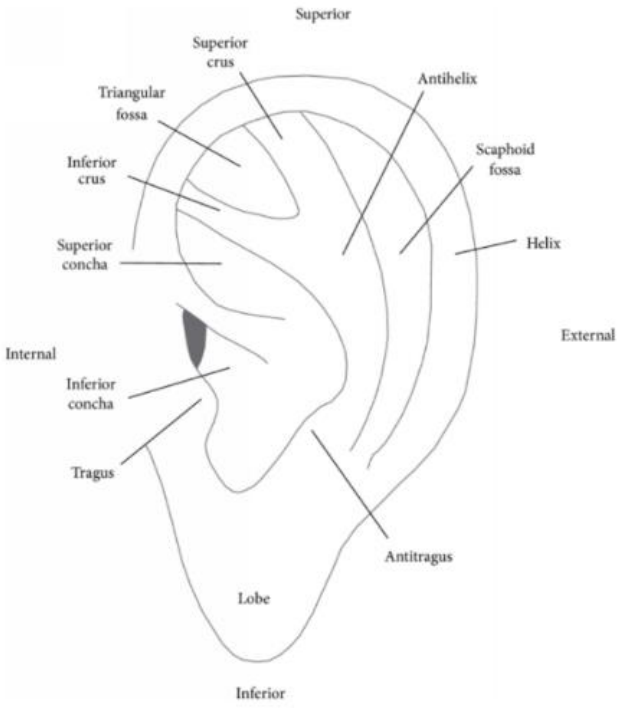


Fig 2: Anatomical structure of ear

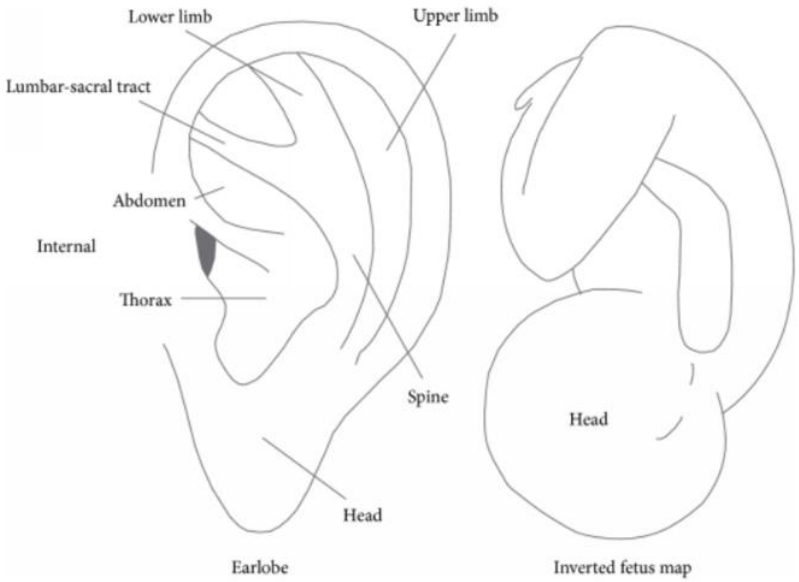


Fig 3: Ear map as like inverted child

The NTS mediates many reflexes, for instance, the carotid sinus reflex (chemoreceptor and mechanoreceptor), the aortic reflex (chemoreceptor and mechanoreceptor), the gag reflex, and the cough reflex, as well as several respiratory and gastrointestinal reflexes regulating organ function . The concha of the auricle and the external auditory canal, especially the inner part of the tragus, is supplied mainly by the ABVN. Stimulation originates from the cutaneous concha through the auricular nerve (CN IIX) and travels to the jugular ganglion, and the branches of the vagus nerve start from this ganglion and end in the NTS of the medulla oblongata (6). Based on the complex connections in the NTS between the brain and the viscera, ABVN stimulation can regulate the ANS.

The stimulus from AA raises the vagal tone and regulates the cardiovascular, respiratory, gastrointestinal, and endocrine systems . Regarding the cardiovascular system, AA can lower the heart rate and blood pressure and accelerate blood flow and heart rate variability (HRV) . Delta Reflex Theory. Delta reflex theory posits that cold or heat stimulation on parts of the body raises the temperature the vagal nerve (6).

1.6 Experiences with Functional Magnetic Resonance Imaging (fMRI).

Gao et al. (2008) proposed that stimulating different points in the earcan induce a similar response on the cardiovascular and gastrointestinal systems (13). Alimi et al. (2002) demonstrate that acupunc- ture in the point of the ear for the hand leads to selectively altered fMRI changes in the somatosensory cortex for the hand of the postcentral gyrus. Romoli et al. (2014) employed fMRI to detect the differences between two stimulated acupoints: Thumb Auricular Acupoint (TAA) to bilateral parietal operculum and the second somatosensory area and Brain Stem Auricular Acupoint (BSAA) to the limbic and cortical areas . Alimi et al. (2014) used fMRI to prove the topography of the French-German auricular area better than the Chinese auricular area (6).

According to traditional Chinese medicine (TCM), frozen shoulder belongs to the blockage group of diseases or to Bi syndrome (painful locomotor disorders). The definition of Bi in Chinese medicine is obstruction or interference with the flow of qi (vital energy) and Blood. It is usually caused

by an invasion of Wind, Cold and Dampness in the intermediate network of channels and collaterals, disrupting related muscle function. The blockage results in pain, aching and stiffness in the muscle, bones, tendons and joints. The sensitive spots on the auricle are anatomically and pathologically related to the affected shoulder joint. In frozen shoulder, the following anatomically related ear acupuncture points are usually used for diagnosis and treatment - shoulder point: at the scapha on the same level as the supratragic notch; shoulder joint point; at the scapha, lying between shoulder and clavicle points; and clavicle point: at the scapha on the same level as the neck point and the junction of the antihelix and antitragus. Additionally, specific ear points are commonly selected for the treatment of specific symptoms. Shenmen point, at the bifurcation of the crura of the antihelix, has a broad-spectrum of action. The stimulation of this point has good sedative, analgesic and anti-inflammatory effects. Adrenal gland point, at the lower projection of the tragus, represents the adrenal gland with the function of regulating the cortical hormones. It is used in treating inflammation and rheumatological symptoms(6).

Previous studies mainly focused on Body acupuncture.But the concept of Auriculotherapy and its therapeutic effect not explored for specific disease condition.In this study we tried to analyse the therapeutic effect of Auriculotherapy in joint degenerative condition. Thus by pricking the above mentioned points was expected to have desired effect on Periarthritic Shoulder

2.0 AIMS AND OBJECTIVES

2.1 AIM:

To assess the effect of auriculoacupuncture in patients with periarthritis of shoulder joint.

2.2 OBJECTIVES:

2.2.1 Primary objective

To assess the shoulder pain and its restriction by SPADI (Shoulder pain and its disability index.

2.2.2 Secondary objective

To assess the range of motion (ROM) of the shoulder by Goniometer

- Flexion
- Abduction
- External Rotation

3.0 LITERATURE REVIEW

3.1 PAS and its effect on ROM and Pain:

Shoulder adhesive capsulitis has different names such as frozen shoulder, scapulohumeral periarthritis, periarthritis of Dupley, periarthritis of shoulder, and check-rein shoulder(14). Neviaser was the one to term the Frozen Shoulder as Adhesive Capsulitis and explore it (14).

It can be defined as an idiopathic condition of the shoulder characterized by the spontaneous onset of pain in the shoulder with restriction of movement in every direction. This pain is often very severe and characteristically, disturbs sleep. In the early stages there is a full range of shoulder movement under an anaesthetic (14).

Neviaser identified that in the early stages of Adhesive Capsulitis, intense hyperaemia of the subcapsular tendon and the synovium happens and in the later stages marked fibrosis of synovium and capsule of shoulder joint along with the thickening and fibrosis of subcapsular muscle (14).

Figure 4: Normal and Pathological changes in the joint capsule

This condition has four stages namely a painful stage, a freezing stage, a frozen stage and a thawing or recovery stage (15).

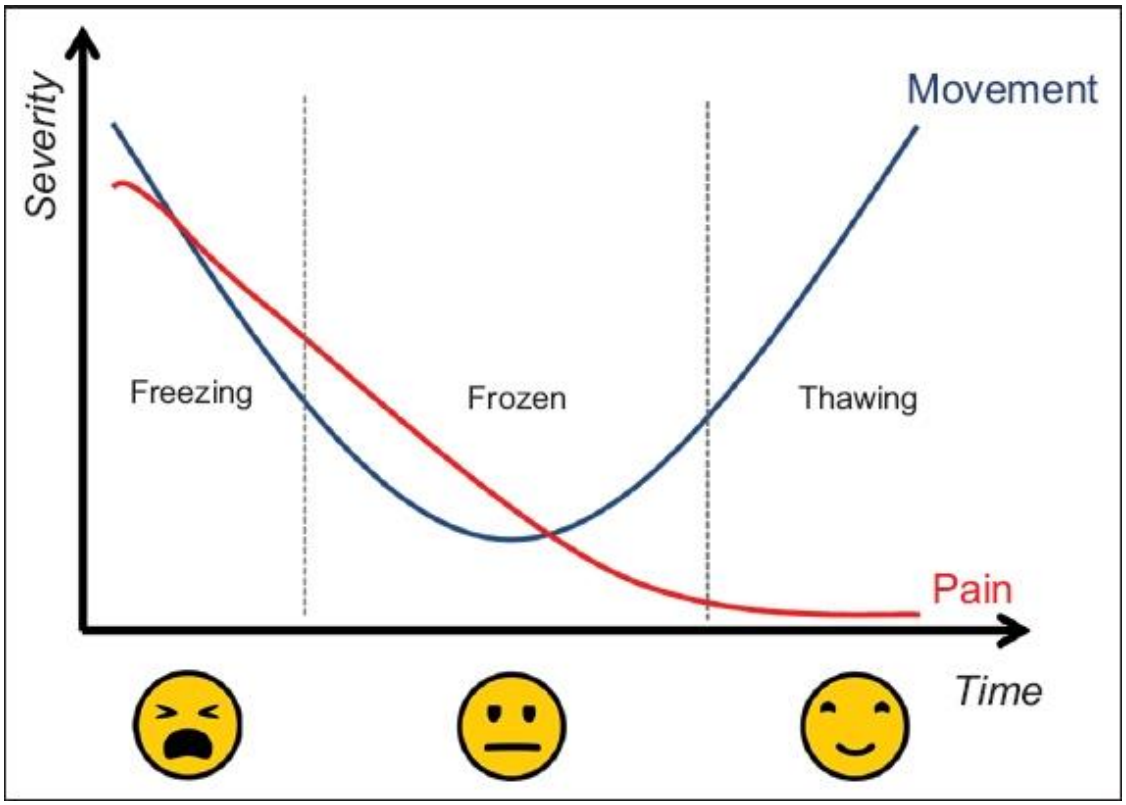
Symptoms of painful stage includes pain and moderate limitation of ROM and it prevails for less than three months. Histological observation at this stage shows Synovitis and capsular hypertrophy. The second stage is the freezing stage severe pain and reduction of ROM, Ipervascular synovitis, disorganized Collagen deposition are characteristics of this stage and it spans from three to six months. Freezing stage is followed by frozen stage where in stiffness is predominant, histological observations shows dense and

hypercellular collagenous tissue, pain may persist and this prevails for nine to fourteen months. Thawing or recovery stage span from fifteen months to twenty-four months wherein the pain is minimal and ROM gradually improves (15).

Table 1: Stages of Periarthritis shoulder

STAGES	**SYMPTOMS**	**LENGTH OF SYMPTOMS**	**HISTOLOGICAL FEATURES**
PAINFUL STAGE	Aching pain and moderate limitation of ROM	Less than 3 months	Synovitis & capsular hypertophy
FREEZING STAGE	Severe pain and reduction of ROM	3 to 9 months	Ipervascular synovitis. Disorganized Collagen deposition
FROZEN STAGE	Stiffness is predominant. Pain may persist.	9 to 14 months	Dense and hypercellular collagenous tissue
THAWING STAGE	Minimal pain and a gradual improvement of ROM	15 and 24 months	Not investigated.

Figure 5 : Chart shows the clinical presentation of frozen shoulder. Icons with facial expressions represent the level of pain of the patient.



3.2 Classification of frozen shoulder:

3.2.1 Primary / idiopathic frozen shoulder:

The underlying etiology or associated condition can not be identified is primary frozen shoulder.

3.2.2 Secondary frozen shoulder:

The underlying etiology or associated condition can be identified is secondary frozen shoulder.

3.2.3. Intrinsic:

In combination with rotator cuff disorders (tendinitis and partial thickness or full thickness tears), biceps tendinitis or calcific tendinitis.

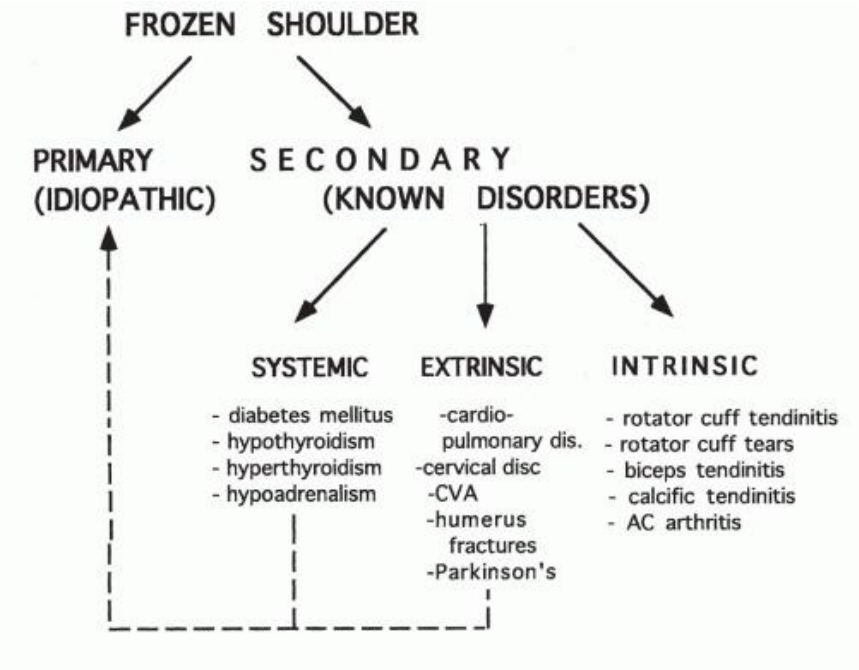
3.2.4 Extrinsic:

In combination with previous ipsilateral breast surgery, cervical radiculopathy, chest wall tumor, previous cerebrovascular accident, or more local extrinsic problems, including previous fracture of the wet shaft, acromioclavicular arthritis, or clavicle fracture.

3.3.5 Systemic:

Periarthritis shoulder associated with diseases such as Diabetes mellitus, Hyperthyroidism, Hypothyroidism, Hypoadrenalism, etc(16).

Figure 6 : Classification of frozen shoulder



3.4. PATHOLOGY AND PATHOGENESIS OF PRIMARY FROZEN SHOULDER:

3.4.1. Joint capsule and ligaments

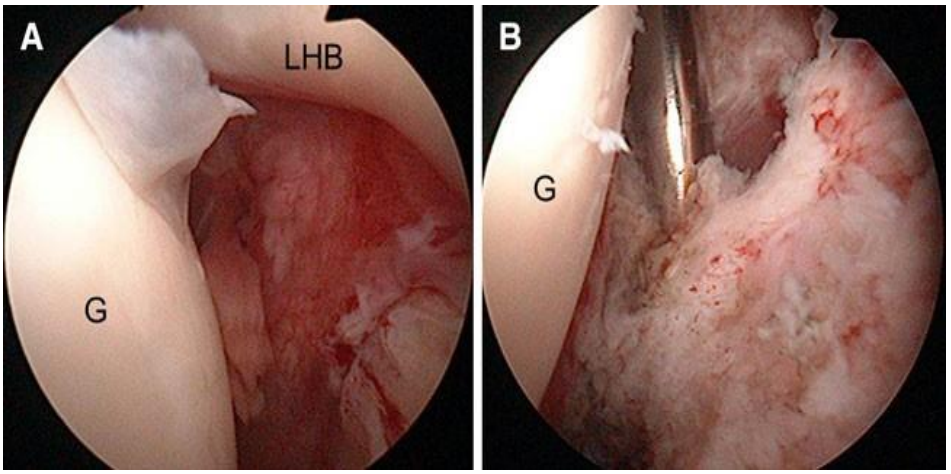
The inflammatory contracture of the joint capsule is the main cause for painful restriction in frozen shoulder. The inflammatory contracture is observed during arthroscopic capsular release in patients process in the joint capsule. The stiffness of frozen shoulder is increased due to progression of fibrosis and it is more than rotator cuff tear(16).

3.4.2. Synovium

Kumagaiet al reported that superficial synovial layers multiplication and interleukin (IL)-1a-positive synoviocytes are absent, emphasizing that primary synovium has no inflammation (16).

In contrast, Rodeo et al. reported that inflammatory cytokines like tumor necrosis factor (TNF)-alpha, IL-1 alpha, IL-1 beta, and IL-6 is present in the FS synovium, along with growth factors such as TGF-beta, PDGF, and fibroblast growth factors (aFGF, and bFGF)also present. Similarly, both fibrinogenic (matrix metalloprotease \MMP -3) and inflammatory (IL-6) cytokines are present in the synovium , thereby inflammatory cytokines are present in both glenohumeral and subacromial FS synovium(16). Hand et al. first demonstrated that B-lymphocytes, T-lymphocytes , macrophages and mast cells present in the synovium and capsule rotator intervals, so that immunological response in FS is seen (17).

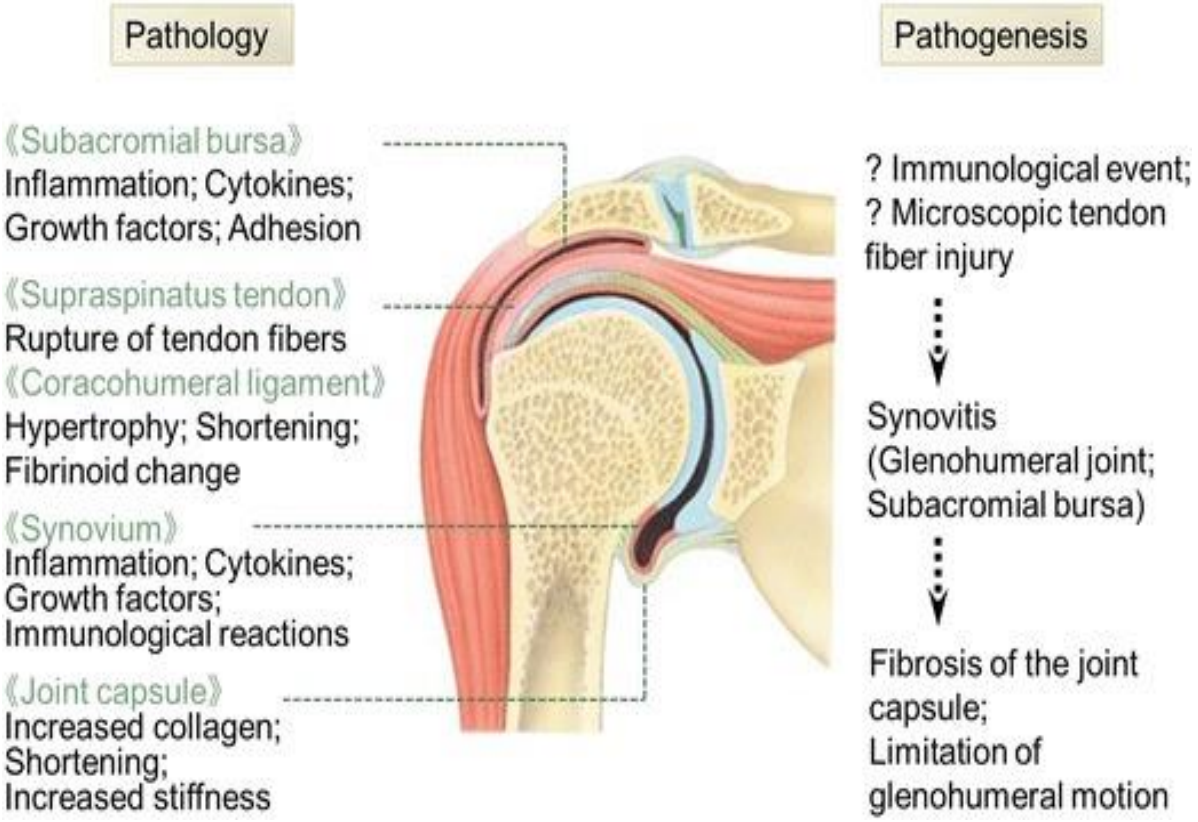
Figure 7 : In a 57-year-old man with primary frozen shoulder, arthroscopic view of the right shoulder. A standard posterior portal inserts the arthroscope. In the anterosuperior region, inflamed synovium is noted.(a). Using an electric cautery, the anterior capsule is being divided (b). Note the thickened joint capsule. G glenoid fossa, LHB long head of biceps



Most studies indicate that both synovial and capsular fibrosis are involved in FS. Because pain precedes stiffness in FS, inflammation is most likely to develop into fibrosis(17).

In both the glenohumeral joint and the subacromial bursa, cytokines such as TNF-alpha and ILs will produce synovitis, whereas matrix-bound TGF-beta may act as a persistent stimulus resulting in capsular fibrosis (16)(17).

Figure 8 :Primary frozen shoulder pathology and pathogenesis. The pathologic findings documented in the literature are listed on the left of the scheme. The possible concept of primary FS pathogenesis is shown on the right.



Due to presence of cells of the immune system, it is assumed that immunomodulated chronic inflammation may have a role in FS pathogenesis(16).

Another possible synovitis initiator is rotator cuff tendon degeneration or injury. Although microscopic, tendon fiber rupture may trigger induction of inflammatory mediators or fibrotic cytokines in the joint of the shoulder.

However, this hypothesis has not been established so far, whereas it is known that partial rotator cuff tear accompanies joint contracture(18).

3.4.3 Molecular biology of frozen shoulder-induced limitation of shoulder joint movements

Molecular biology researches of frozen shoulder mainly emphasize on pathological process of inflammation and fibrosis. The present molecular biological studies have shown that inflammation and fibrosis are the basic pathological changes of frozen shoulder. Still the precepitative cause for frozen shoulder is still unclear and it can be

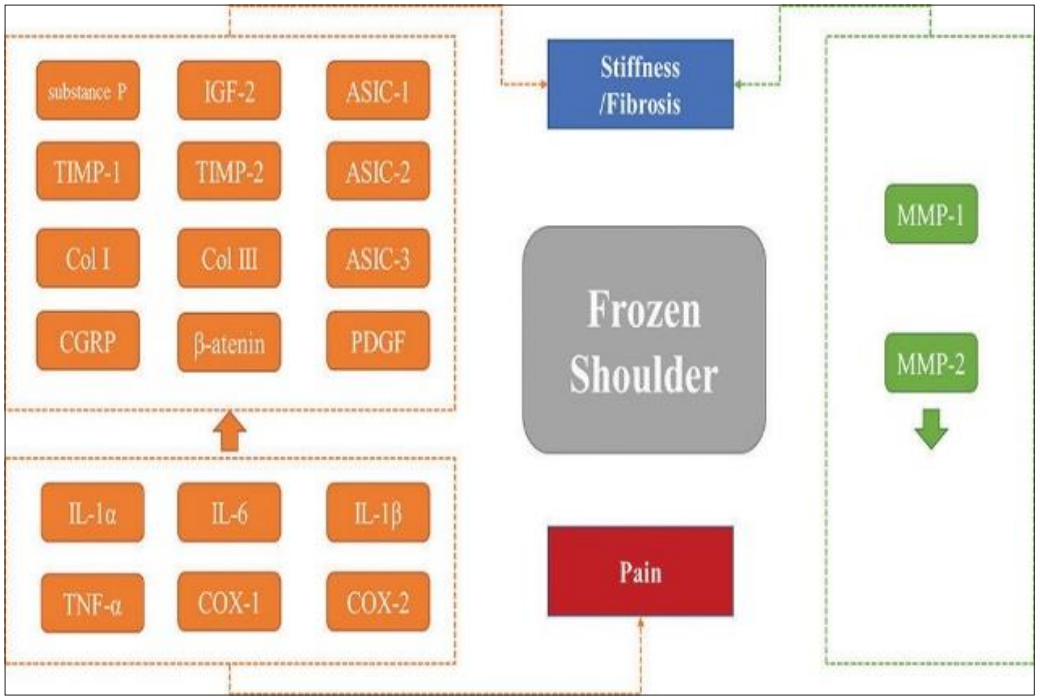
- Immune reaction
- degenerative changes
- microinjury etc

Inflammatory mediators such as COX-1, COX-2, IL-1, IL-6, TNF-α, etc can play a significant role in induction, regulation, and remission of inflammation. Inflammation causes

- Adhesion
- Edema
- Pain which leads to decreased activity of the shoulder joint and consecutive fibrosis of the shoulder joint and thickening and adhesion of the shoulder capsule.

Certain Cytokines like IGF-2, ASIC, TGF-β, MMPs, and TIMPs may contribute to the fibrotic changes in frozen shoulder. The balance disorder between TGF-β and MMPs can have a important role in development of fibrosis in frozen shoulder. They contribute to increased expression of collagen Type I and Type III, fibrosis and the shoulder joint, contracture and thickening of the shoulder capsule, and eventually limitation of shoulder movements (19).

Fig 9 : Cytokines and proteins related to the stiffness and pain in frozen shoulder. The orange color indicates that the expression is elevated, and the green color indicates decreased



3.5. CLINICAL PRESENTATION:

The significant feature of frozen shoulder is decreased range of motion and shoulder pain. The pain in PAS is often referred to as profound and poorly

localized. If the pain is localized, it is present in the anterior or posterior capsule. The ache can radiate to the region of the shoulder. When overhead, away and back, patients can have progressive pain and severe suffering. Weakness is frequently associated with discomfort or concomitant tendonic disease. On the affected hand, crepitus may be present. Sleep may be disturbed.

Patient's capability to perform self-care and occupational activities are affected by range of motion impairments. Although AC is self-limiting condition, within 3 years most patients have spontaneous resolution, some patients suffer restricted shoulder motion and long-term pain well beyond 3 years (14).

3.5.1. DIFFERENTIAL DIAGNOSIS:

If the patient presents with stiffness and painful shoulder, the following condition should be considered for differential diagnosis.

1. Acromioclaviculararthropathy,
2. Autoimmune diseases such as

a) Systemic Lupus Erythematosus,

b) Rheumatoid Arthritis

3. Biceps Tendinopathy
4. Glenohumeral Osteoarthritis
5. Neoplasm
6. Rotator cuff tendinopathy or tear (with or without impingement)

7. Cervical disk degeneration

8. Subacromial and Subdeltoid bursitis(14).

Table 2: Differential Diagnosis of Adhesive Capsulitis:

Table 1. Adhesive Capsulitis: Alternative Diagnoses

Condition	*Distinguishing physical examination findings*	*Distinguishing histologic findings*	*Diagnostic tests*
Acromioclavicular arthropathy	Positive cross-arm adduction and compression testing; glenohumeral range of motion is preserved	Localizes over acromioclavicular joint (superiorly); history of repetitive overuse (e.g., weight lifting)	Plain radiography
Autoimmune disease (e.g., systemic lupus erythematosus, rheumatoid arthritis)	Malar rash; synovitis (tenderness and effusions) in other joints	Multisystem involvement; multiple joints involved	Antinuclear antibody testing; rheumatoid factor test
Biceps tendinopathy	Tenderness over long head of the biceps tendon; positive Speed or Yergason test	Localizes anteriorly	MRI (radiography may determine whether calcifications are present)
Cervical disk degeneration	Limited range of motion in neck and pain with active movement; intrinsic hand weakness; impaired light touch	Localizes posteriorly; hand numbness and weakness in radiculopathy	Cervical spine radiography
Glenohumeral osteoarthritis	Similar to adhesive capsulitis; shoulder girdle atrophy may be present	History of shoulder trauma or surgery; older age	Plain radiography
Neoplasm	Similar to adhesive capsulitis	Fevers, night sweats, unexplained weight loss (if advanced); dyspnea or cough (if Pancoast tumor present)	Plain radiography, MRI
Rotator cuff tendinopathy or tear, with or without impingement	Passive range of motion is preserved; painful arc, focal tenderness, positive Hawkins and Neer tests	Possible history of repetitive overuse; often localizes anteriorly or laterally	MRI (radiography may determine whether calcifications are present)
Subacromial and subdeltoid bursitis	Passive range of motion is preserved	Possible history of repetitive overuse	Diagnostic subacromial lidocaine (Xylocaine) injection, MRI

NOTE: *Secondary adhesive capsulitis can also result from these conditions.*

MRI = magnetic resonance imaging.

3.6. Physical Examination:

Patients with chronic PAS may lose their arm swing naturally during walking. Atrophy of the tissue of the shoulder girdle may be noted. Impaired movement of the glenohumeral joint can lead to unusual movement of the scapular with effective forward flexion. A person with PAS may be physically

uncomfortable and need short rest or a mild loosening of his hand to show the exercises.

Palpation may result in unclear, diffuse sensitivity over the anterior and shoulder. A particular structure is rarely focally tended, with differential diagnoses or concurrent pathologies such as rotator cuff or biceps tendinopathy suggested.

PAS susceptibility can be raised when flexion, abduction, and external rotation were restricted. Examination of the both shoulders can reveal the accurate assess deficits of the affected side. Initially, patients must actively study movement boundaries and the doctor may passively support scapular stability if loss of movement is noted to guarantee precise movement measurement (14).

3.7. Conventional Interventions

3.7.1 Steroid injection

One of the top key interventions for PAS is steroid injection. Numerous Cochrane studies have found that there is a extremely varying possible place of a subacromial or blind glenohumeral injection.

Recent Cochrane study brings together the results from twenty-six heterogeneous research and finds that steroid injection alone for PAS has a tiny short-term advantage, but the proof is unclear (20).

3.7.2 Anti-inflammatories

In the therapy of PAS, the use of anti-inflammatory drugs or corticosteroids is essential. It is possible to use non-steroidal anti-inflammatory medicines (NSAIDs) to alleviate pain at any point. No proof has shown that NSAIDs alter the PAS prognosis. NSAID's, however, are engaged not only in anti-inflammation intervention, but also in generating analgesic effects. So, the main option for PAS can be sensible.

In addition, no comparison research was conducted with placebo or natural history of PAS on oral corticosteroids. Most trials have shown that corticosteroids can decrease suffering compared to treatment or placebo, but their results are not sustained in the lengthy run (21).

3.7.3 Intra-articular corticosteroid injections

While high-quality corticosteroid injection RCT has not been performed for the therapy of PAS, the accessibility of some proof on intra-articular injections indicates that their use has a short-term advantage. Minimal complications such as subacromial injection or glenohumeral injection may be regarded when using this invasive operation.

The injection limitation is blind with 60 percent inaccuracy. Advanced clinical practice may contribute to higher accuracy. Using imaging methods such as ultrasound-guided joint injection can solve this restriction (21).

3.7.4 Capsular distension injections

Under local anesthesia this method of therapy should be performed. In order to extend the sac, affected joint is injected with local anesthetic. Often this method is poorly accepted due to discomfort encountered during the intra-articular implant operation. Thus, injections of capsular distention may be unknown (22).

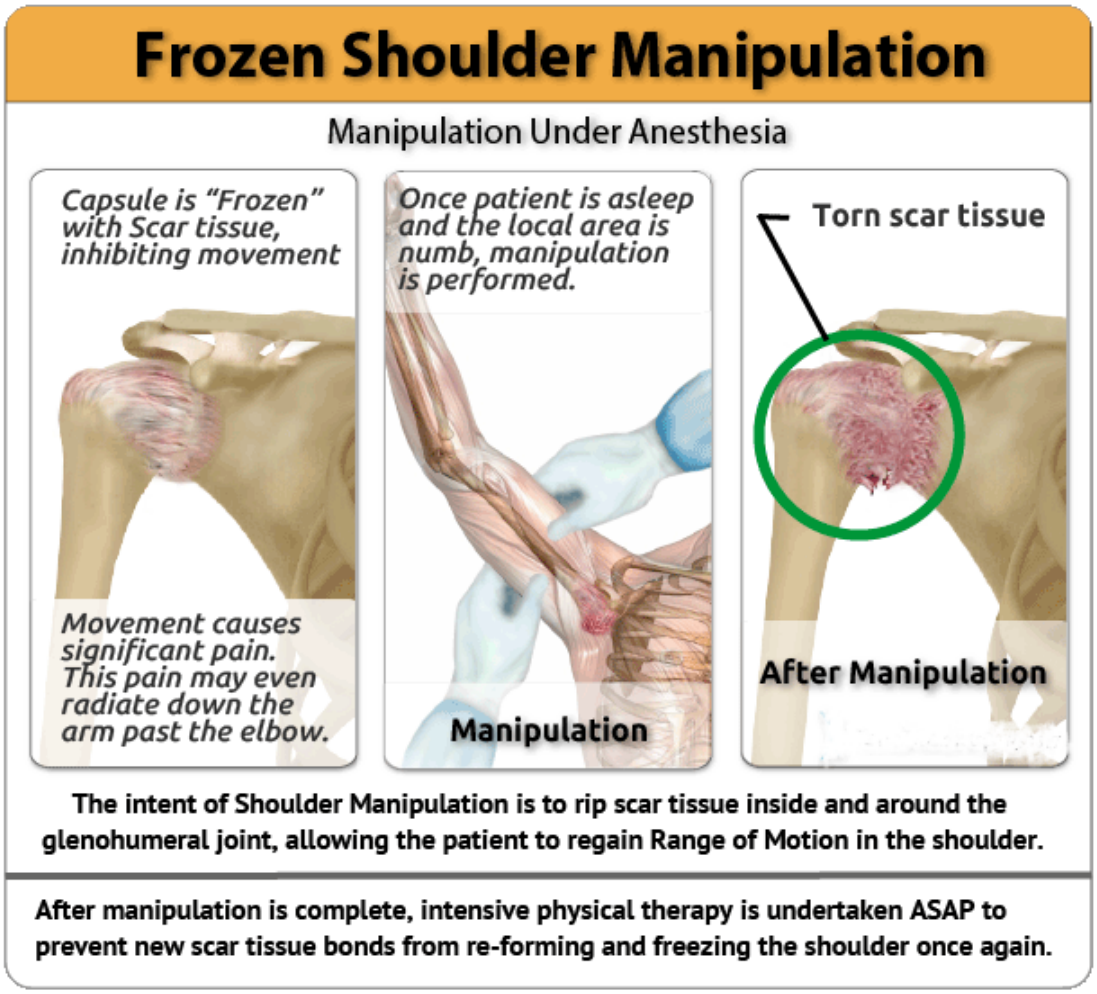
3.7.5.Surgical treatment

PAS therapy should lead to surgical therapy only after no advancement has been made with conservative management. There is no clear time limit for operation to occur. As a general rule, after getting some type of conservative management for at least 2 months, if nurses does not notice any advancement in symptoms and patient present with important discomfort and constraints may undergo surgical action (22).

3.7.6. Manipulation under anesthesia:

Manipulation under anesthesia technique enables the working theater to restore the shoulder ROM. This technique may require immediate postoperative physical treatment. Manipulation disadvantage is pain following recovery from anesthesia. It may occur due to muscles extended during anesthesia manipulation. This can possibly be a slow method of regeneration. It induces further surgical pain to the shoulder when added with surgical discharge and can trigger slow recovery (21).

Fig 10 : Frozen shoulder manipulation



3.7.7.Arthroscopic release and repair

An additional tool to address the shoulder with PAS is arthroscopy. Essential infections on the impacted organ are strengthened coracohumeral ligament and rotator cuff interval with the contracted sac including the axillary sac. Using arthroscopic tools, these buildings can be maintained.

The shoulder ROM can be retained with manipulation under arthroscopic discharge if needed. You can execute the discharge either before, during, or after the manipulation.

To achieve access to the joint, the manipulation may need to precede the method. Arthroscopy also enables the shoulder and its anatomy to be fully evaluated. Any disease not diagnosed may be a problem (23).

3.7.8.Rehabilitation

The efficacy of PAS rehabilitation has been observed in several studies. In general, most studies show different degrees of pain, ROM and function improvement following different methods of treatment (24).

3.7.9. Patient education

PAS is so painful and the resolution progresses very slowly. The slow prognosis and inclusion of PAS compliance should be trained to patients wherever possible. If you know and understand beforehand that symptoms can be fully solved for several years, apprehension and urgency for a functional return may decrease (24).

3.8.Traditional Chinese Medicine:

According to ancient Chinese medicine the sensitive spots on the auricle area unit anatomically and pathologically associated with the affected spheroid joint. A body part is not moved, and the vital energy (qi) will not circulate through it. It becomes stiff and painful when it comes to the shoulder joint.

In harmonizing body (yin), spirit (yang) and vital energy ,physical exercise plays a major role , which is essential in turn for the internal harmony between the various organ systems as well.

The Qi does not circulate in the body, which will lead to stagnation and if a body part is not moved, the joint becomes stiff and painful and if it is in the shoulder joint it is PAS. In harmonizing both body (Yin) and mind (Yang) as well as Qi (Qi), physical exercise is important for the clearance and activation of meridians and collaterals.

For the inner harmony between different organ systems as well as between the body and the natural environment, physical exercise is essential. The blockage group or syndrome of Bi belongs to the frozen shoulder (painful locomotive disorders). There are four types of Bi syndrome:

i. **Wandering Bi:**

The wind prevails, either externally or internally. The outside wind usually invaded the body, while the inside may result from qi failure disrupting the muscle function associated with it. The obstruction leads to muscle pain, dullness and rigidity, bones, tendons and joints, or blood deficiency.

A fluttering pain in the joints of the extremities with rigidity is characteristic of the syndrome. The main reason for this is an outer wind attack. A thin, white, sticky, covered tongue and a superficial, swinging and fast pulse may be present. The wandering Bi syndrome patient usually reacts to windy weather.

ii. **Painful Bi:**

Cold prevails, as the arthralgia responds to warmth and cold, particularly in winter without inflammation. The cold may be outside or inside. A severe, stabbing, joint pain with steepness is characteristic. A thin white tongue may be coated and a deep, narrow pulse may be present.

iii**. Fixed Bi:**

in which humidity prevails. It is characterized in the surrounding tissues by joint rigidity and mild, fixed pain associated with numbness. Cloudy and/or wet weather usually causes the syndrome. The patient may have a coated yellow tongue and a fast, rolling pulse.

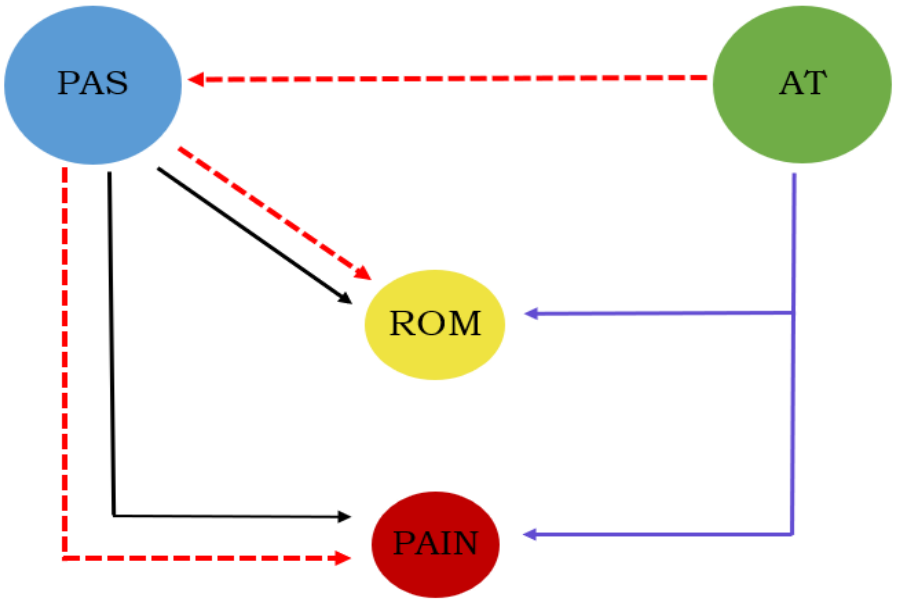
iv. **Febrile Bi:**

Where heat prevails and where wind, cold and steam turn into heat. Chronic severe pain, local redness, tenderness and swelling characterize the arthralgia in this syndrome.

There are also major symptoms of fever and thirst. The cardinal signs of inflammation may involve one or more joints: heat, redness, and swelling. The patient may have a dry, yellow-coated tongue and a fast pulse that rolls.

The acupuncture treatment of the frozen shoulder shall disperse the excess wind, cold and steam and remove the obstruction of the affected meridians and their collaterals by spreading qi and blood(25).

Figure 11: schematic representaion of relation between ROM ,PAIN and AT in PAS



Represents lack of literature about the relationships between auriculotherapy and clinical features of PAS

Represents previous reported studies about PAS

Represents relationship of auriculotherapy on Range of motion and pain

3.9. Auriculoacupuncture (AA) or Auriculotherapy (AT):

Auricular acupuncture is a special acupuncture form and is often used as a complement to acupuncture in the body. It is based on a model of thought contained in itself. A key idea is the somatopy concept. This expression

consists of the Greek word soma (= body) and topos (= location) and means the body's differentiated mapping in one area (here the auricula). The body's representation on the ear calls a vaguely inverted fetus to mind (26).

3.9.1. History of Auriculotherapy:

Since ancient times, therapeutic procedures involving the auricles have been mentioned. Thus, Hippocrates is said to have tried to cure impotence by bloodletting from the outer ear; Egyptian sailors are said to have tried to improve their navigational sight by pricking their ear lobes (the Eye Point is also found in the ear lobe, among other things, in the modern auriculotherapy model).

Auricula cauterization has been undertaken time and time again as a therapy for sciatic pain. For example, we know about applications from Persian healers. But references to such therapeutic approaches are also available in Western Europe.

ZactusLusitanus described ear cauterization as a therapy for sciatic pain in Portugal as far back as 1637; for the same reason Ignaz Colla described cauterization of the rear side of the auricula in 1810. In 1717, through the auricula, Valsalva treated toothache. There are observations about treatment in the area around the auricula in the Huang Di Nei Jing's second part (Ling Shu).

Many publications reported the advantages of cauterizing the auricula as a therapy for sciatica as early as the 18th century. It wasn't until 1950

however that the French neurologist Paul Nogier tried to write a comprehensive description of the auricula therapy. In numerous patients treated by a healer (Mme.Barrin) for sciatic pain, he discovered cauterization marks on the anthelix.

With this therapy, the patients reported amazing success, leading Nogier to further investigate the phenomenon.He also started his own cauterization trials, but then turned to "less barbaric" methods such as pricking with needles or pins, achieving equally good results.

He came to the conclusion that body disturbances (over and above sciatic pain) could be regularly demonstrated through sensitive or painful auricula points. He interpreted the body representation on the auricula as an inverted fetus image.

Hence he was able to assign the representation zone L4 to the point on the antihelix usually used for sciatic pain therapy (26).

3.9.2.Auricular Innervation Zones and Embryological Assignment According to Nogier

- The auricular branch of the vagus nerve
- The auriculotemporal nerve of the trigeminalnerve
- The great auricular nerve of the cervical plexus.

The vagus nerve's auricular branch internalizes the concha. The "ectodermal" organs are projected here according to this concept. The lobule is supplied by the large auricular nerve of the cervical plexus, the outer helical

rim up to about the Darwinian tubercle, and the back of the ear. These areas match the organs in the layer of ectodermal germs. The remaining part of the ear, and by far the largest, is innerved by the trigeminal nerve's auriculotemporal nerve. Here are projected the mesodermal organs (26).

3.9.3. Overview of the anatomy of auricle (aa)

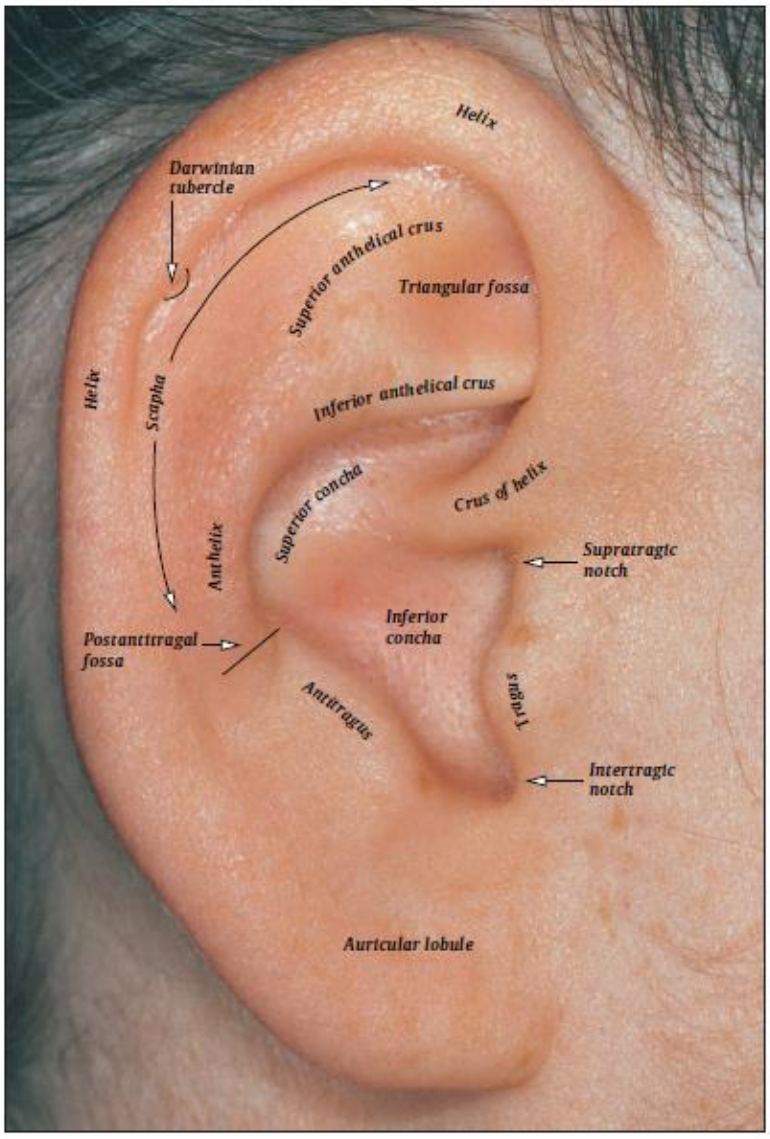


Figure 12: The anatomy of auricle

The health disorders that are commonly associated with each part of the auricle when there is pathology in a particular anatomical organ are presented next.

Helix

Anti-inflammatory points and treatment of allergies and neuralgias.

Helix Root

Dysfunctions of one's external genitals, sexual disorders, urinary dysfunctions, and diaphragmatic problems such as hiccups.

Helix Arch

Allergies, arthritis, tonsillitis, and anti-inflammatory processes.

Helix Tail

Representing the dorsal horn, sensory neurons of the spinal cord, and the preganglionic sympathetic nervous system, this region is used for the treatment of peripheral neuropathies and neuralgias.

Antihelix

Treatment of problems related to the main torso of the body that are related to pain and tension associated with the musculoskeletal system.

Superior Crus

Disorders of the lower extremities of the leg and foot.

Inferior Crus

Low back pain, lumbosacral disorders, buttocks spasms, and sciatica.

Antihelix Body

Thoracic spine back problems, chest pain, shingles, and problems with the abdominal muscles.

Antihelix Tail

Neck pain, disorders of the cervical spine, and throat problems.

Lobe

Dysfunctions related to the cerebral cortex of the brain, uncomfortable facial sensation, eye disorders, jaw pain, and dental analgesia. The ear lobe further represents conditioned reflexes, psychological resistances, and emotional blocks.

Tragus

Problems with the corpus callosum, appetite control, and adrenal glands.

Antitragus

Frontal, temporal, and occipital headaches.

Intertragic Notch

Hormonal disorders of the pituitary gland control of other glands.

Scaphoid Fossa

Problems in the upper extremities, such as frozen shoulder, stiff arm, tennis elbow, sprained wrist, hand tremors, and aching fingers.

Triangular Fossa

Problems in the lower extremities, such as hip pain, knee injuries, sprained ankle, foot pain, cold feet, uterus dysfunctions, and pelvicorgan problems.

Concha

Visceral organ disorders.

Superior Concha

Disorders related to abdominal organs, such as the dysfunctions of the pancreas, gall bladder, kidney, and urinary bladder.

Inferior Concha

Disorders related to thoracic organs, such as heart problems and lung disease. It is also used for the treatment of substance abuse.

Concha Ridge

Disorders related to the stomach and liver.

Concha Wall

Dysfunctions associated with the thalamus of the brain, including general pain, sympathetic nerve problems, and vascular circulationdisorders.

Subtragus

Laterality problems, auditory nerve deafness, and internal nose and throat disorders.

Internal Helix

Dysfunctions related to the internal genital organs, kidney disorders, and allergies.

Posterior Ear

Disorders related to motor activity and problems with the musculoskeletal body, such as muscle spasms and motor paralysis.

Posterior Lobe

Dysfunctions of the pyramidal motor cortex, the extrapyramidal striatal system, cerebellar tremors, and eye twitches.

Posterior Groove

Pain and muscle spasms of paravertebral muscles.

Posterior Triangle

Problems with motor control of leg movement, leg muscle spasms, and leg motor weakness.

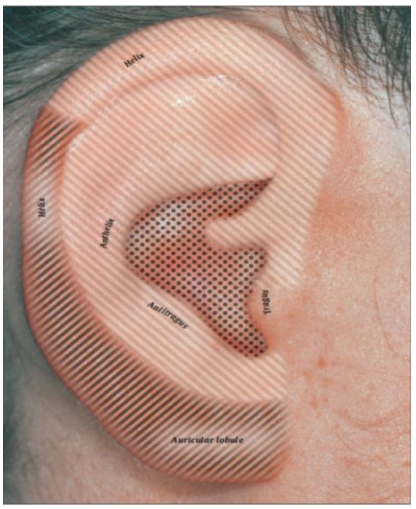
Posterior Concha

Problems with motor control of internal organs (27).

3.9.4.According to Nogier, the different zones are assigned to different functional areas:

- Entodermal zone - Metabolism, organs
- Mesodermal zone - Motor system
- Ectodermal zone - Head and central nervous system

Figure 13 : different zones acc. to Nogier.



3.9.5.Zones of Auricular Innervation According to R.A. Durinjan:

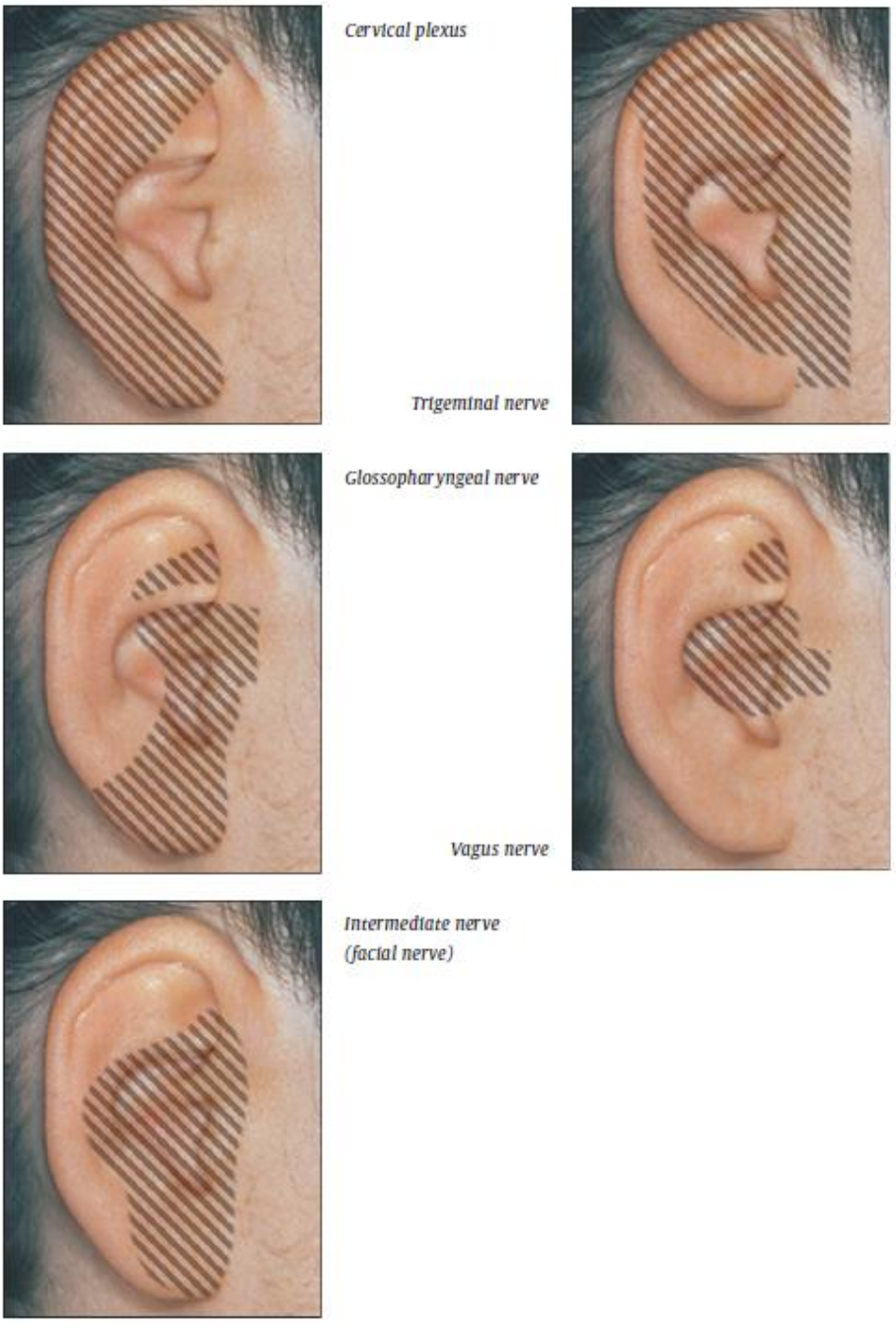
1. Fibers of the cervical plexus,
2. The trigeminal nerve,
3. The intermediate nerve of the facial nerve,
4. The glossopharyngeal nerve,
5. The auricular branch of the vagus nerve.

The innervation zones show distinct overlaps of the five participating nerves between all areas. Therefore, no auricular zone is inherited exclusively by a single nerve. This may explain why on identical anatomical sites two or more acupuncture points of different functions are projected.

Similarly, the same organ projections are attributed to different location sites. For example, we find projections that match the organ's parenchyma, next to them projections of the corresponding nervous innervation, and finally projections that represent the organ's functional state. It is conceivable that the overlaps of the innervation zones also vary individually due to the variation in auricular shape.

Therefore, the frequently described points are actually zones rather than points where the actual acupuncture of the ear has to be searched according to individual circumstances. This approach goes without a doubt back to Nogier, who tried to find individual representations of acupuncture points through the Auriculocardiac Reflex (ACR) (26).

Figure 14: Zones of Auricular Innervation acc. to R.A. Durinjan



3.9.6. Topographic Location of Reflex Zones on the Auricula:

A particular pattern follows the distribution of ear acupuncture points on the auricula. The location of individual organs or body regions is the same as that of an inverted fetus:

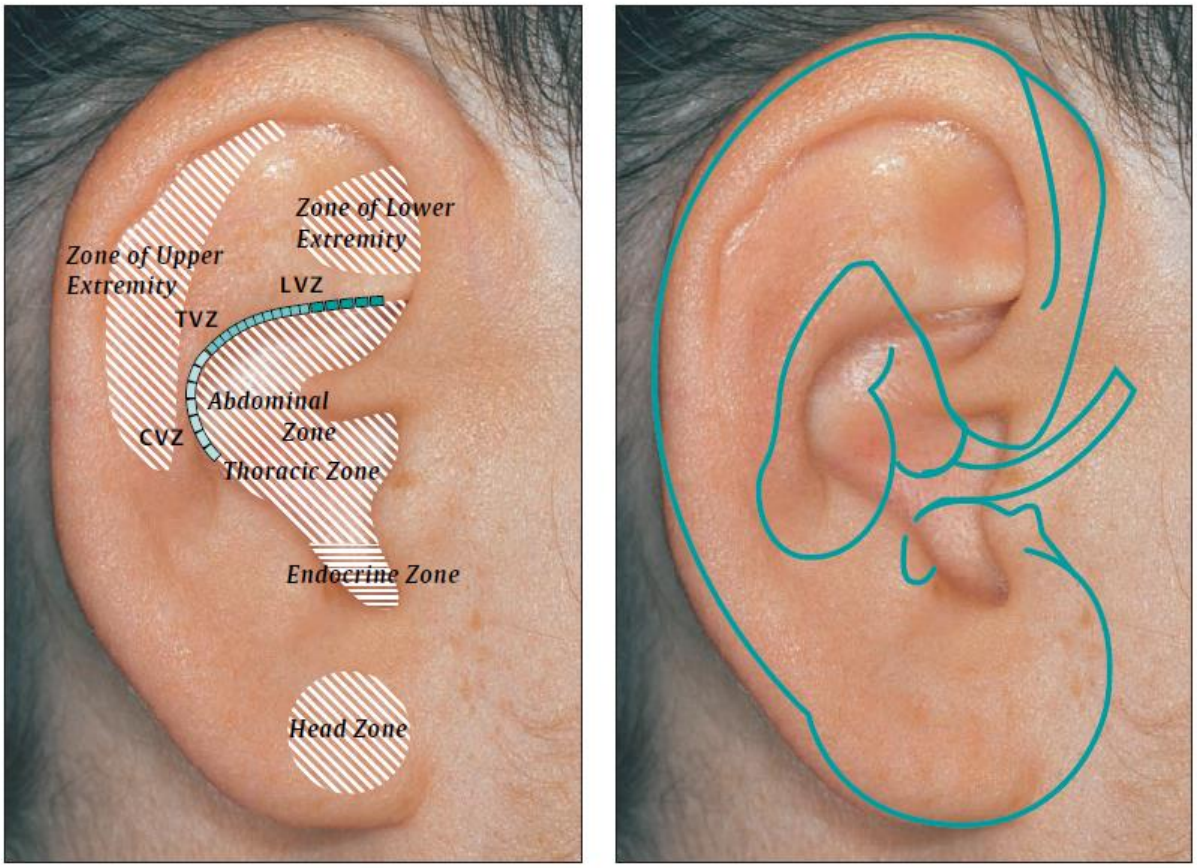
- The points in the ear lobe area are related to the face and head.
- The upper extremity of the scapha is projected.
- The anthelix and anthelicrura points are related to the body's trunk and lower extremity.
- The internal organs in the concha cavity are projected.
- The lower extremity is projected in the triangular fossa, according to Nogier; the pelvic organs are projected here according to the Chinese school.
- A sympathetic innervation of the intestine is projected on the helix crus, according to Nogier. The Chinese school is assigning the diaphragm to this area.

The hormonal activity-related points are also assigned differently: Chinese school describes only an endocrine region, while Nogier differentiates between the adrenal gland's hypothalamic projections and the thyroid gland.

There is no contradiction between these slightly different anatomical circumstances; they can be understood as different reaction sites. Here we can differentiate between functional and organ-specific pathologies. Nogier's points can often be assigned to organ-specific pathologies, while more functional relationships are described by the Chinese school.

The motor elements are projected on the auricula's back and the sensory elements on the auricula's front, according to Nogier. Thus, on the front of the ear, the motor zone of an organ at the back of the ear is exactly opposite to that organ's sensory zone(26).

Figure 15 : Topographic Location of Reflex Zones on the Auricula:



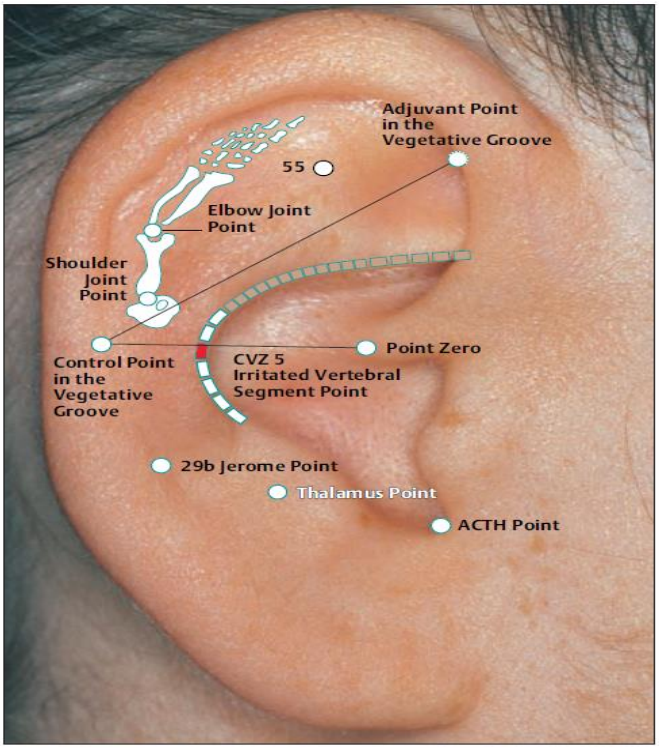
Localization of organs and extremities according to the inverted fetus model.

3.9.7. Shoulder Joint Disturbances:

These subsume diseases ranging from purely functional to major structural changes and are roughly summarized under periarthritis scapulohumeral.

After an unusual physical strain, a simple subacromial bursitis can be treated more successfully than a chronic impingement syndrome caused by a rotator cuff break. In this regard, an orthodox medical diagnosis is imperative in the treatment of shoulder girdle diseases in evaluating the prospect of success of the planned acupuncture(26).

Figure 16 : specific auriculo points for PAS



3.9.8 Acute disturbances

In the case of acute disturbances, treatment is performed through Nogier's shoulder representation zone, supplemented by shen men [55] with their anti-inflammatory activity and Jerome Point [29b] with their muscle relaxing activity. The Thalamus Point is used under severe pain condition(26).

3.10. AA on Pain management:

AT is used to treat different types of pain such as postoperative, dental, and musculoskeletal pain, as well as anesthesia-related pain. Activating the descending pain inhibitory pathway of the brainstem, thereby inhibiting the ascending pain pathway, induces the analgesic effects of AT. AT application can activate the descending pain inhibitory pathway along the spinal cord's dorsal side where the dorsal horn cells are located, exerting a pain-relieving effect. Thus, by suppressing the dorsolateral funiculus in the spinal tract, deep brain stimulation can produce analgesic effects (6).

Nociceptive pain may trigger hypothalamus, periaqueductal gray, somatosensory cortex, and prefrontal cortex activity, but deep brain stimulation may also activate the same subcortical thalamus regions to produce analgesic effects. This stimulation induced analgesic effect increases beta endorphin concentration, and naloxone can block it (6).

Taguchi et al. (2002) found that AA reduced the requirement for anesthetics (i.e. desflurane) by around 8.5% . Greif et al. (2002) found that the auriculo electric Stimulation resduced the anaesthetic requirement by 11% .

Allais et al. (2011) found that when improving migraine,by using the Auriculopoints were more effective than other points which has no significance because auriculo points correspond to our body's somatotopic representation on the ear .

Usichenko et al. (2005, 2007) found that in 120 patients who underwent outpatient knee surgery, AA helps to reduce the consumption rate of ibuprofen. And also, in the patient receiving total hip arthroplasty, Usichenko et al. (2005) found that the administration of Auriculo Acupuncture results in consumption rate of piritramide (6).

AA has been found to be a beneficial and safe treatment for low back pain (LBP)[66–68]. Suen and Wong (2008) found that AA's longitudinal effects in elderly people with LBP enhance disability, pain and sensation, and functional activity(28). Hunter et al. (2012) found that patients in the AA group exercise reported greater changes in the Oswestry Disability Questionnaire (about 10.7% in points) compared to the group of exercise-only patients at the end of the follow-up period of 6 months (28).

A pilot study was conducted by Wu et al. (2014) to assess the effects of AA on insomnia patients with hemodialysis. The results showed significant declines in the Pittsburgh Sleep Quality Index (PSQI) scores for sleep quality, sleep latency, sleep disturbance, daytime dysfunction, and reduced medication intake (29).

3.11.AA on ROM:

Auricular acupressure applied to the Shenmen (TF4) and Subcortex (AT4) acupoints can also improve the range of motion of the knee after the operation. This effect can be explained primarily because auricular acupressure produced an analgesic effect, allowing patients to have a better compliance with the treatments designed to improve the range motion in the knee. A literature search revealed no acupressure studies and only one acupuncture study in a TKR patients (30).

4.0 MATERIALS AND METHODS

4.1 Subjects

A total sixty subjects of both gender with age ranging between 40 – 65 years were participated in the study.

4.1.1 Description of the subjects and selection of samples

Totally 64 subjects were screened out of which 60 subjects were recruited based on Inclusion criteria & Exclusion criteria and 4 subjects didnot meet the screening criteria were excluded from the study. Participants were randomly assigned into 2 groups –Experimental group(n=30) and control group(n=30). The Subjects were recruited from the Government Yoga and Naturopathy Medical College and Hospital, Arumbakkam, Chennai-106.

4.1.2 Demographics:

Table 3 : Describes the demographic details of the subjects

Contents	Experimental Group	Control Group
Age (Mean ±SD)	**52.2±4.7**	**50.3±2.96**
Subjects	30	30
Sex (Male/Female)	14/16	13/17

SD – standard deviation

4.2 Ethical Considerations

4.2.1 Ethical Clearance

Ethical clearance was sought from the Institutional Ethics Committee prior to the start of the study and the approval for the same was granted.

4.2.2 Written Informed Consent

Subjects who fulfilled inclusion criteria were apprised about the purpose of the study and their rights as research subjects. Informed consent form was administered in English and regional language Tamil. Sufficient time was given to each patient to go through the information sheet and their queries were answered. Their right to withdraw anytime from the study and the need for willingness to participate voluntarily in the study was explained. All the subjects expressed their willingness to participate in the study by giving a signed informed consent.

(A sample consent form and case sheet is enclosed as **Annexure I and II** respectively)

4.3 Screening of the subjects

4.3.1.Inclusion criteria:

1) Shoulder pain for at least 1 month and less than 12-month duration

2) Appreciable restriction of both active and passive motions with abduction and flexion not exceeding 90° and external rotation not exceeding 30°

3) Pain at night, with inability to lie on the affected side.

4) Age between 40 years and 65 years.

5) Receiving no treatment in the last 4 weeks.

6) Agreeing to cooperate with doctor's instructions of acupuncture.

7) Providing written inform consent.

4.3.2.Exclusion criteria:

Participants will be excluded if they have:

1) History of major shoulder injury or surgery.

2) Clinical or radiological evidence of other pathologies that could possibly account for symptoms.

3) Patients with evidence of cervical radiculopathy, paresis, or other neurological changes in the upper limb on the involved side

4) Presence of underlying fracture associated inflammatory arthritis, known renal or hepatic disease, haematopoietic disorder, and malignancy, any mental disorder likely to interfere with the course or assessment of the disease process.

5) Painful arc between 40° and 120° abductions indicative of rotator cuff disease

6) Uncontrolled diagnosed neurological diseases, immunodeficiency, bleeding disorders, and allergies.

7) Patient receiving acupuncture currently or received acupuncture 2 weeks prior to enrollment.

8) Women in lactation, pregnant women, or with plans to get pregnant in the coming half year.

10) Patients undergoing other trials.

4.4.Study Design

4.4.1.Type of the design: Prospective Randomized control study.

4.4.2.Randomization:

In this trial, subjects were randomly assigned to either experimental group or control group. Randomization was done using the online random number generating tool at the website – www.random.org. Each random number was carefully concealed by the principle investigator, not permitted to unfold until eligible patients were included in this trial with written informed consent. After a patient was enrolled in the trial, the researcher requested patient to open one of the concealed envelopes to further assign to either experimental group or control group.

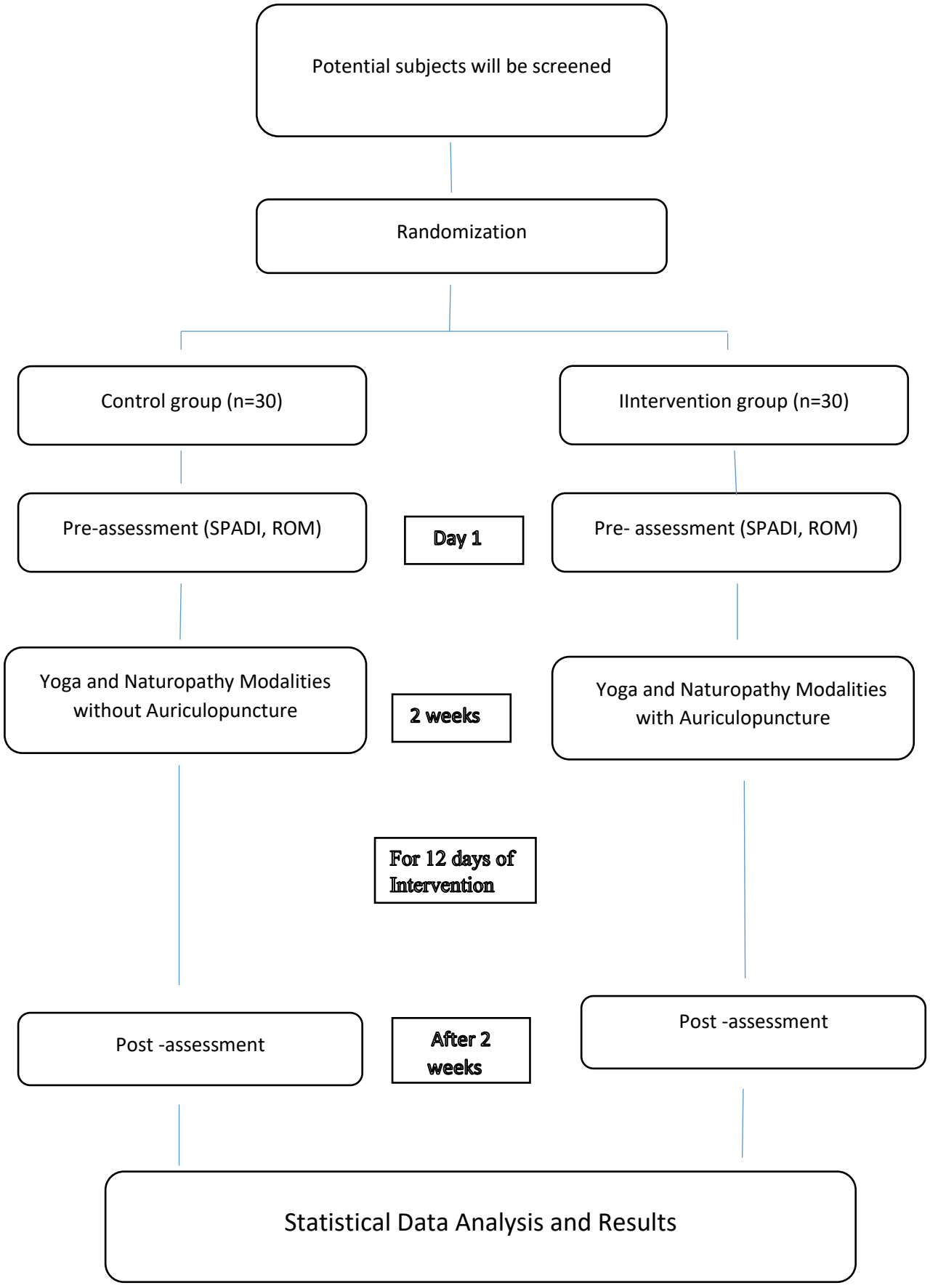
4.4.3.Data points:

The data was collected at baseline at day 1 (before treatment) and post data was extracted after completion of 12 sessions.

4.4.4.Trial Profile:

The trail profile illustrates the study plan, flow of patients across data points, statistical analysis of data and results.

Figure 17 : ILLUSTRATION OF STUDY PLAN



4.5.Assessments

The baseline and post-intervention assessments consisted of:

Table 4: List of Primary and Secondary outcome variables

	PRIMARY OUTCOME VARIABLES
	Shoulder pain and its disability index (SPADI)
	SECONDARY OUTCOME VARIABLES
	Range of Motion (ROM) of Shoulder Joint
i.	Flexion
ii.	Abduction
iii.	External Rotation.

4.5.1 Primary Outcome Variables

4.5.1.1.Shoulder pain and its disability index (SPADI).

The Shoulder Pain and Disability Index SPADI are formulated to measure present shoulder pain and disability in an outpatient setting. It is a self- administered questionnaire that consists of 13 items that assess two domains; pain (pain symptoms, 5 items) and disability (physical function, 8 items). The items of both domains were scored on a visual analog scale (VAS) ranging from 0 to 10, where 0 = no pain/no difficulty and 10 = worst pain imaginable/so difficult required help.**(117)** Domain scores was equally weighted, then added for a total percentage score ranging from 0 to 10, where 0 = best and 10= worst.

Subjects were assessed twice in this study. Questionnaire was administered to the patient at the baseline after inclusion for the study and after completion of 12 sessions.

Instructions to the subjects and scoring

Subject was instructed to read the question carefully and asked them to mark circle on the score for each item that best represented their experience of their shoulder problem.(31) Subscale was summed and transformed to a score out of 10. Percentage was calculated out of each sub scale and also for the total score. A mean was taken of the two subscales to give a total score out of 10, higher score indicating greater impairment or disability. In each subscale patients are advised to mark only one item. If the item was not applicable to them and they are requested to pass to next question. Percentage was calculated by excluding the unanswerable item from the total score. If a patient marks more than two items that item was considered as non-applicable, no score was given.(A SPADI questionnaire is enclosed as **Annexure III**)

4.5.2 Secondary Outcome Variables

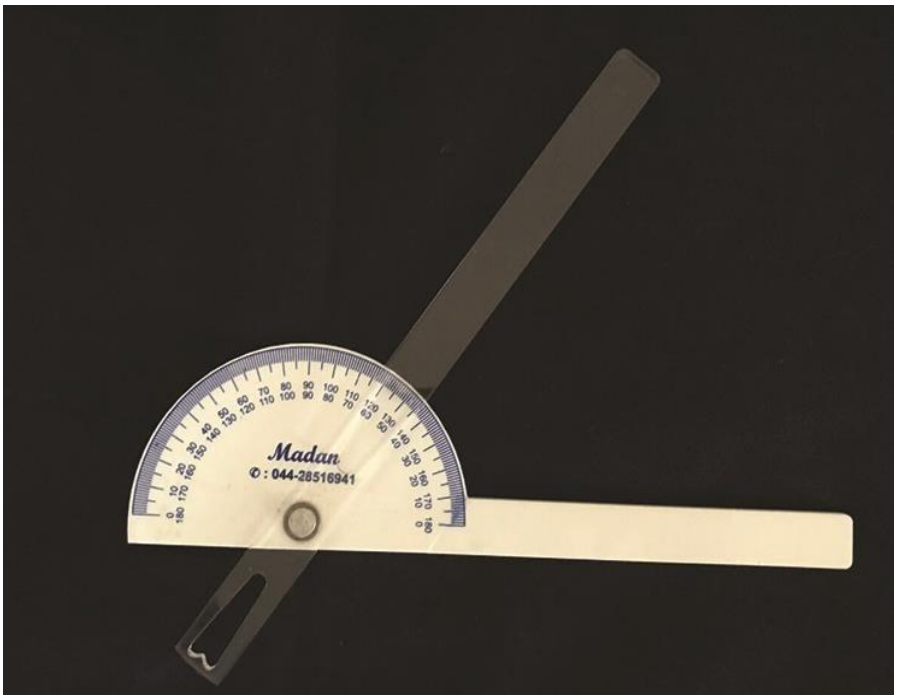
4.5.2.1 Range of Motion

Ranges of motion (ROM) measurements are essential for the evaluation and diagnosis of PAS. ROM is usually measured by using goniometer. The term goniometry is derived from two Greek words, *gonia* meaning angle and *metron*, meaning measure. Thus, a goniometer is an instrument used to measure angles.

Goniometers are produced in a variety of sizes and shapes and are usually constructed of either plastic or metal. We have used plastic goniometer for this study. Within in the field of physical therapy, Goniometry is used to measure the total amount of available motion of the specific joint. Goniometry can be used to measure both active and passive range of motion.

The patient was positioned on examination table for the testing. We explained about the examination of their affected shoulder joint. Active range of motion (aROM) of flexion, abduction and external rotation was assessed at neutral position.

Figure 18: Goniometer



Subjects were assessed twice in this study with Goniometer. The range of motion of shoulder was measured with Goniometer at the baseline after inclusion for the study and after completion of 12 sessions.

4.5.2.a Shoulder flexion

Shoulder flexion is also referred to as forward flexion. Shoulder flexion is the motion of the shoulder when lifting the arm in front of the body over the head. Range of motion is measured with the side of the body and the arm straight. It is measured from neutral to the highest point the arm can be lifted over the head. We have advised the patient to do active ROM without any strain. Normal range of motion is 180 degrees.

Figure 19: Examination of Shoulder flexion

Figure 20 : Measuring shoulder flexion using goniometer

4.5.2.b Shoulder abduction

Abduction is a term that refers to a body part moving laterally away from the body. For the shoulder joint, it refers to the arm swinging out from the side of the body, in an arm-flapping motion.

Range of motion is measured with the palm facing the side of the body and the arm held straight. It is measured from neutral and the arm hanging close to the body at the side of the thigh to the maximum point the arm can be lifted. We have instructed the subjects to lift as much they can. Normal range is 150 degrees

Figure 21 : Examination of shoulder abduction

Figure 22 :Measuring of shoulder abduction using Goniometer

4.5.2.c External Rotation

External rotation is also referred to as lateral rotation. It was measured in a neutral position with the shoulder adducted, the elbow flexed at the right angle, and the forearm parallel to the ground; the angle between the long axis of the forearm and the sagittal plane of the trunk was determined as aROM of external rotation of shoulder joint. They were measured under the instruction that subjects should move their arm as far as they could. Normal range of motion is 90 degrees

Figure 23 : Examination of shoulder external rotation

Figure 24: Measuring of shoulder external rotation using goniometer

4.6 Intervention:

4.6.1 Experimental Group:

Auriculotherapy was given to the 30 subjects along with Yoga and Naturopathy treatment modalities for 12 days. The sterile acupuncture needles were inserted in the ear of the subjects at specific points for 20 minutes of duration.

4.6.1.a General description about specific Auriculotherapy points:

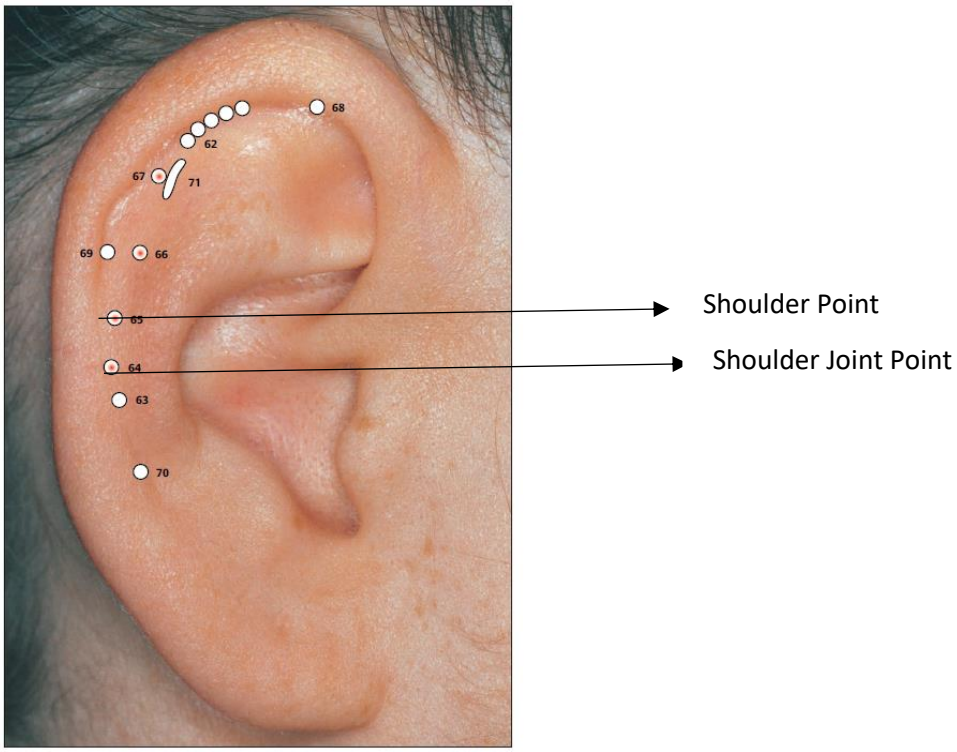
Shoulder Joint Point:(26)

In the scapha, roughly at the level of the lower edge of the root helix.

Shoulder Point:(26)

In the scapha at the level of the elongation of the upper edge of the ascending helix branch to the helix.

Figure 25 : Shoulder Point and Shoulder Joint Point:



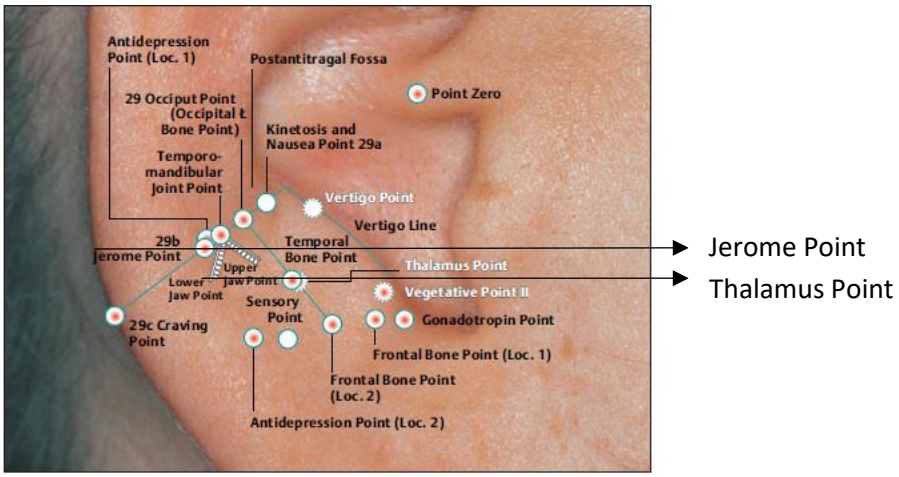
Jerome Point:(26)

In the postantitragal fossa, at the intersection with the Vegetative Groove.

Thalamus Point:(26)

On the inside of the antitragus, opposite the Temporal Bone Point.

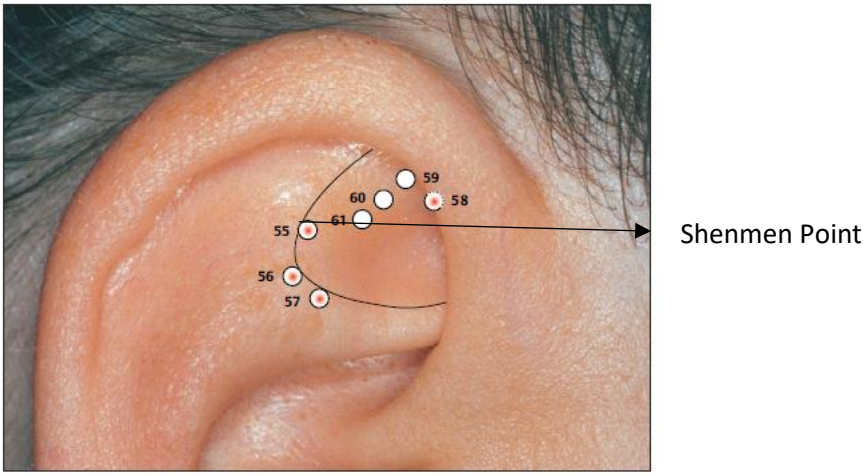
Figure 26 : Jerome Point and Thalamus Point:



Shenmen Point:(26)

In the angle formed by the superior and inferior anti helical crura, more towards the superior antihelical crux.

Figure 27 : Shenmen Point:



4.6.1.b Acupuncture needles:

In this study we have used 0.5 t-sun sterile needles and no needles were reused. Used needle were destroyed through electric needle destroyer.

Figure 28: Acupuncture Needles (½ t-sun)

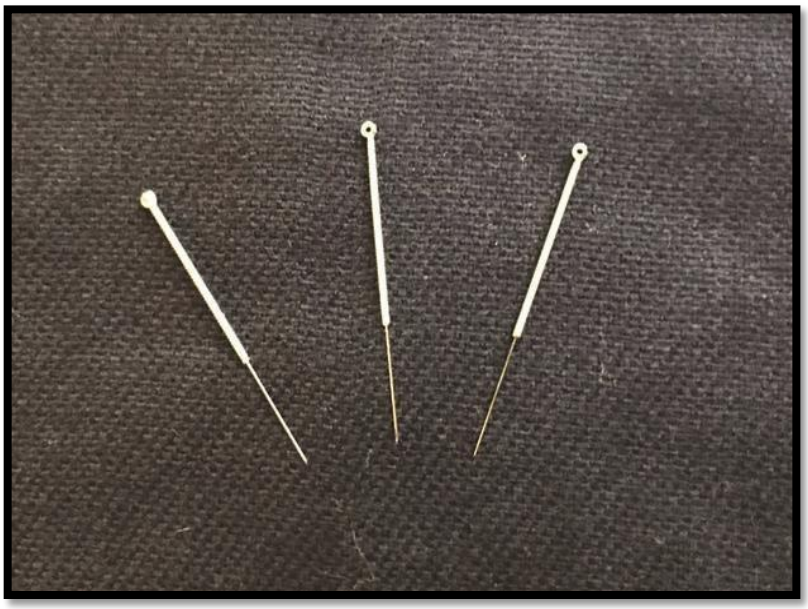


Figure 29 : Needling of specific Auricular Points:

Figure 30 : Needling at the prescribed points

4.6.2 Control Group:

For the 30 subjects of control group, Auriculotherapy was not given. They have undergone only Yoga and Naturopathy modalities.

4.7 Data extraction & analysis

4.7.1 Data Extraction:

The data was collected as primary outcomes and secondary outcome variables. The assessments were done on the before intervention starts (baseline data) and after completion of 12 session (post data). The data was organized in Microsoft Excel Sheets. (Version 2010)

4.7.2 Data Analysis:

Data were analysed using IBM SPSS 18.0. Data was tested for normality Shapiro-Wilk test and found to be non-normally distributed. Hence Mann Whitney U test was performed to assess the significant different between the two groups.Wilcoxon Signed Ranks Test was performed to analyse the difference within the group. Results within the group compared with pre and post intervention was found to be significant ($p<0.5$) for all the variables i.e. pain index, disability index, total SPADI score, shoulder flexion, abduction and external rotation

5.0 RESULTS

The study was conducted to asses the effect of auriculo acupuncture in patient with periarthritis shoulder designed as experimental group and the control group.The Experimental group measured with primary and secondary variables. Primary variables are shoulder pain and disability index (SPADI), secondary variables are Range of Motion of the shoulder flexion, abduction and external rotation. Data were collected at baseline and labelled as Pre-treatment value and after 12 sessions in 14 days as Post treatment scores. Data was tested for normality Shapiro-Wilk test and found to be non-normally distributed. Hence Mann Whitney U test was performed to assess the significant different between the two groups.Wilcoxon Signed Ranks Test was performed to analyse the difference within the group. Results within the group compared with pre and post intervention was found to be significant ($p<0.5$) for all the variables i.e. pain index, disability index, total SPADI score, shoulder flexion, abduction and external rotation in both control group and experimental group. Mann Whitney U test performed to find out the difference between the Experimental group and control group. Results showed that auriculotherapy group was significant in both statistically and clinically in pain index *($P<0.00$)*, disability index *($P<0.002$)*, total SPADI score *($P<0.001$)*, shoulder flexion *($P<0.001$)*, abduction *($P<0.002$)* and external rotation *($P<0.00$)*.

Table 5: Results of Primary Outcome Variables

	Experimental Group (n=30)		Control Group (n=30)		*p* Value
	Mean ±SD		Mean ±SD		
	Pre	Post	Pre	Post	
Pain Index (%)	79.56±5.74	56.53 ± 6.65	79.75 ± 6.266	72.92 ± 5.47	*0.00*
Disability Index(%)	80.87 ± 4.289	55.90 ± 8.54	80.87 ± 4.45	73.24 ± 5.08	0.002
Total Score (%)	68.383 ± 4.99	62.14 ± 6.61	77.05 ± 4.47	71.15 ± 4.71	*0.001*

% - Percentage, SD – Standard deviation, *p* – Probability

Figure31: Comparison of SPADI – Pain Index (%) in a bar diagram

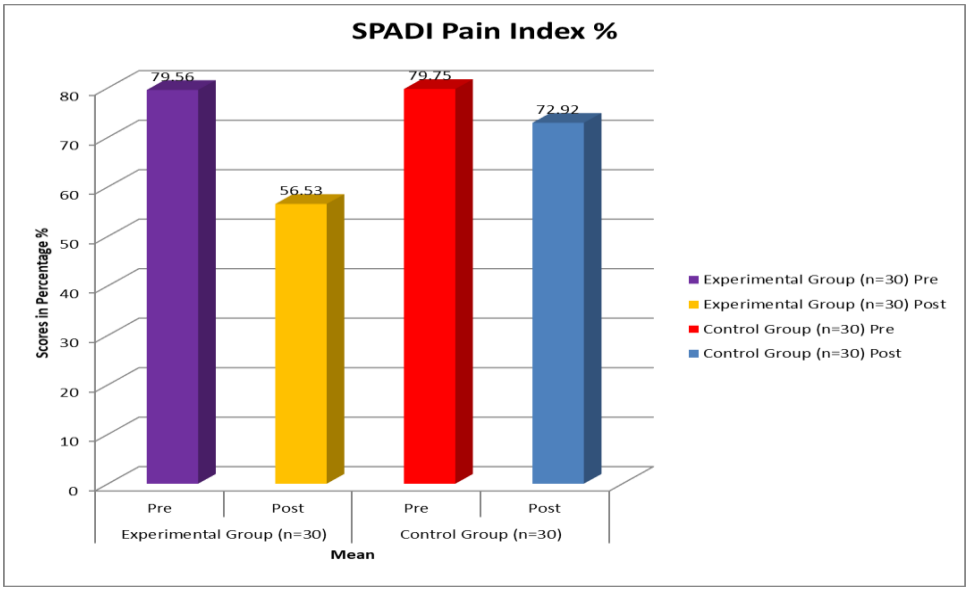


Figure 32: Comparison of SPADI – Disability Index (%) in a bar diagram

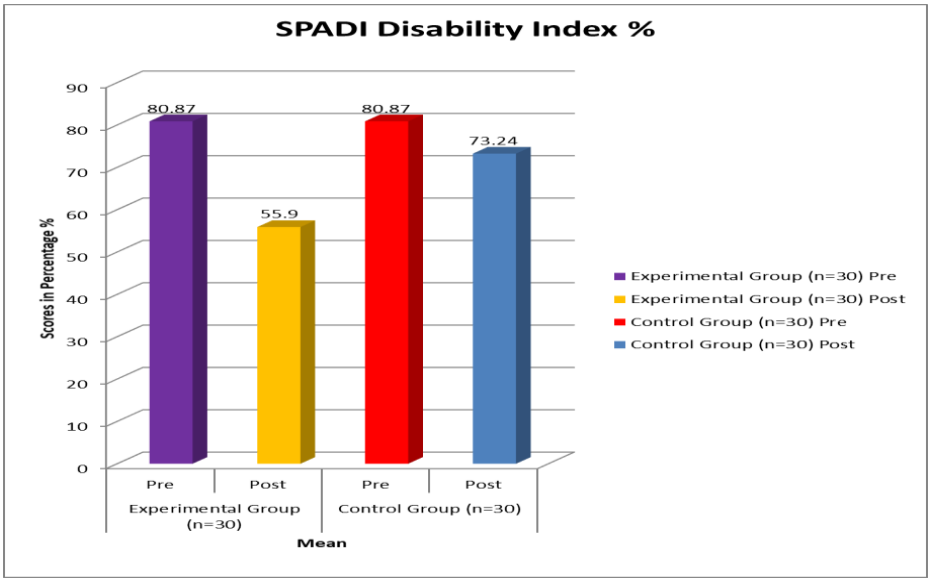


Figure33: Comparison of SPADI – Total score (%) in a bar diagram

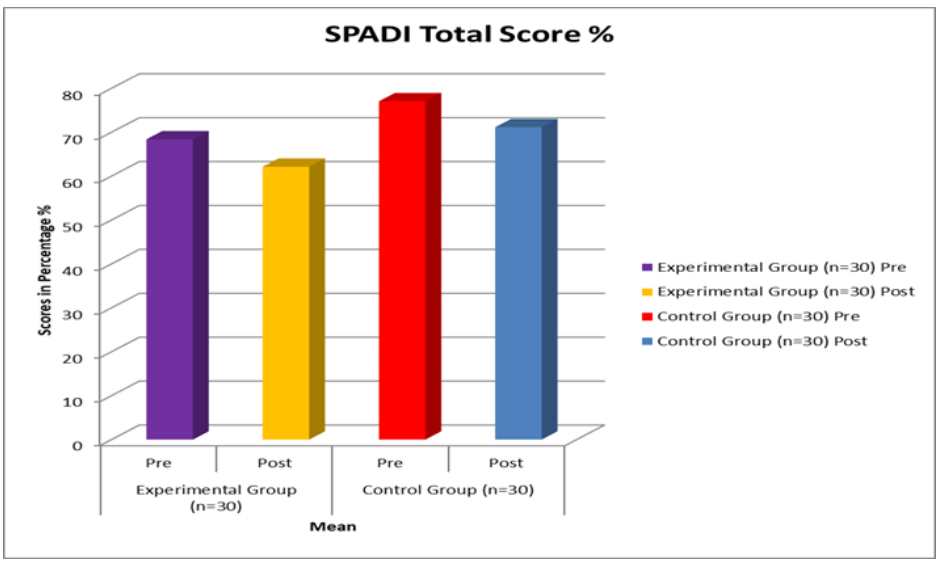


Figure 34:Results of primary outcome variables (%) in a bar diagram

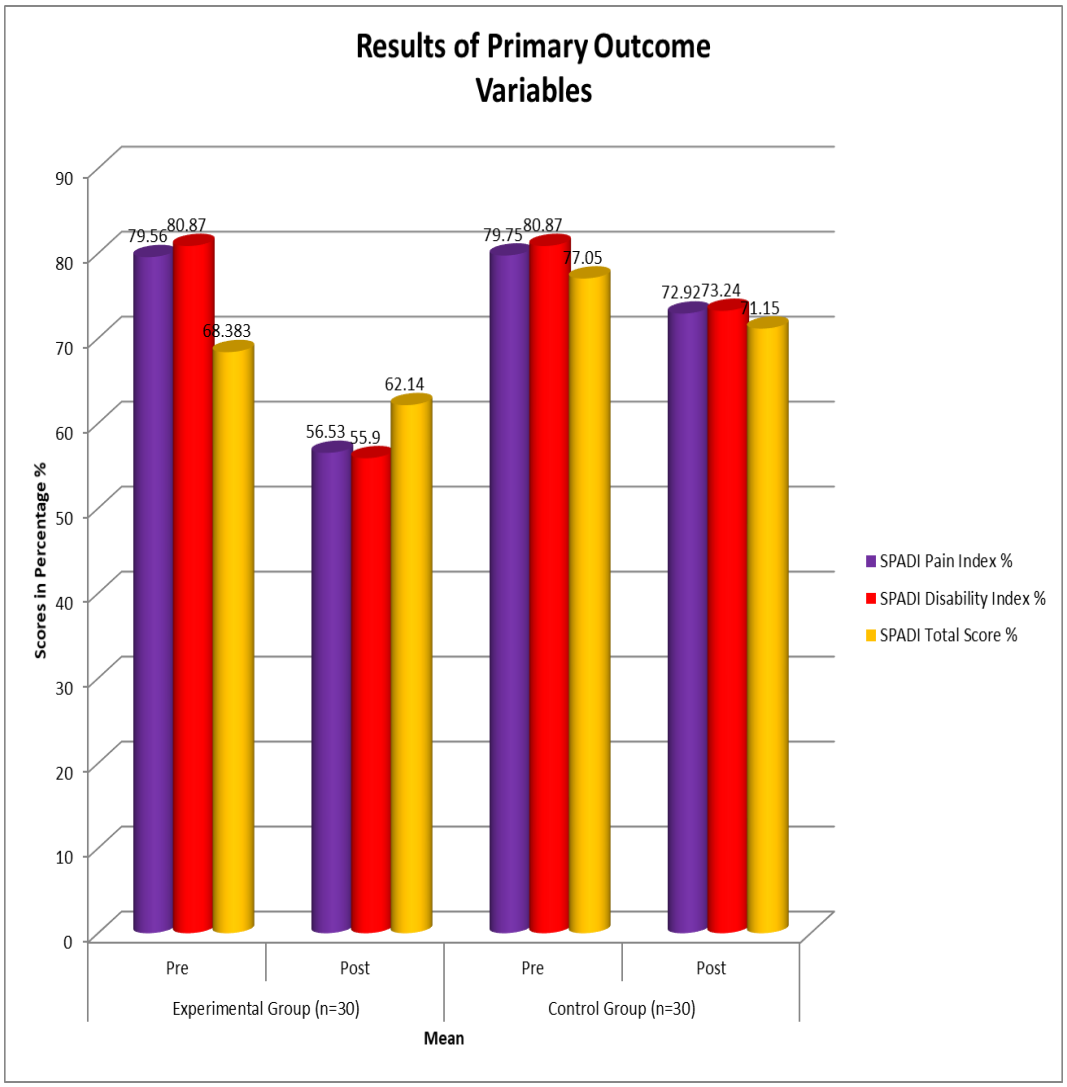


Table 6: Results of Secondary Outcome Variables

Variables	Experimental Group (n=30)		Control Group (n=30)		*p* Value
	Mean ±SD		Mean ±SD		
	Pre	Post	Pre	Post	
Shoulder Flexion	81.27 ± 4.05	112.07 ± 10.19	81.67 ± 2.78	90.07 ± 3.84	0.002
Shoulder Abduction	82.13 ± 4.32	118.13 ± 10.9	80.80 ± 3.18	90.37 ± 5.87	0.001
Shoulder External Rotation	26.40 ± 1.773	41.40 ± 4.52	25.97 ± 1.35	32.13 ± 3.0	0.00

Figure 35:Comparison of ROM-Shoulder Flexion (%) in a bar diagram.

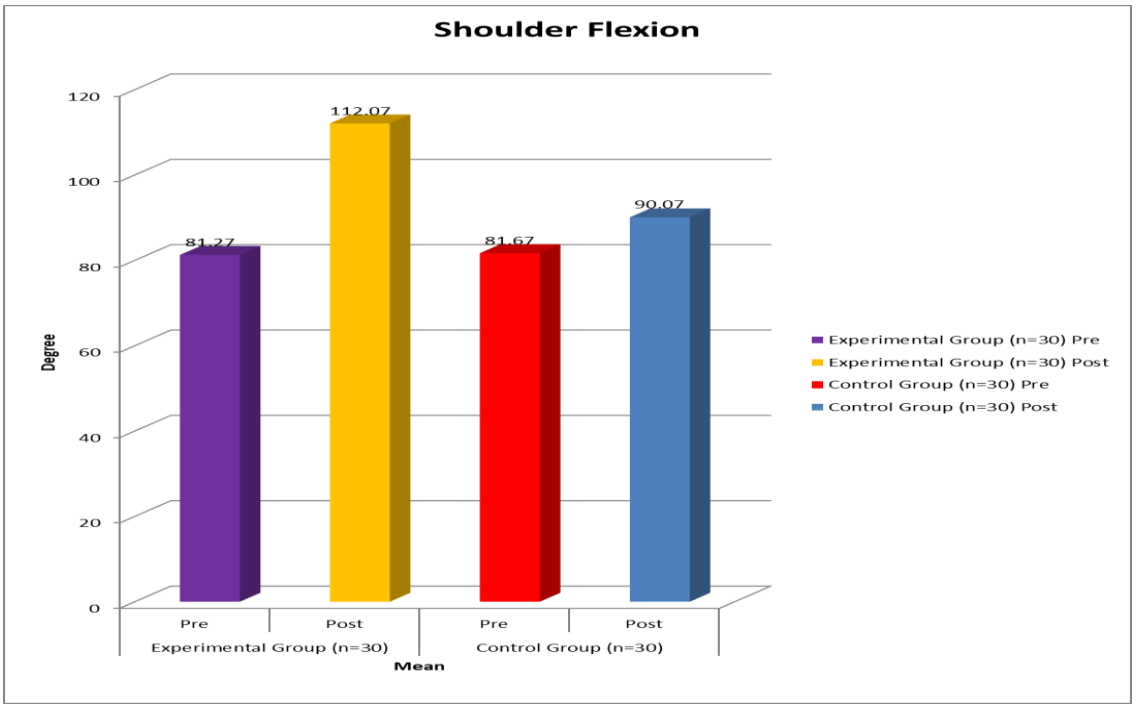


Figure 36:Comparison of ROM-Shoulder Abduction (%) in a bar diagram.

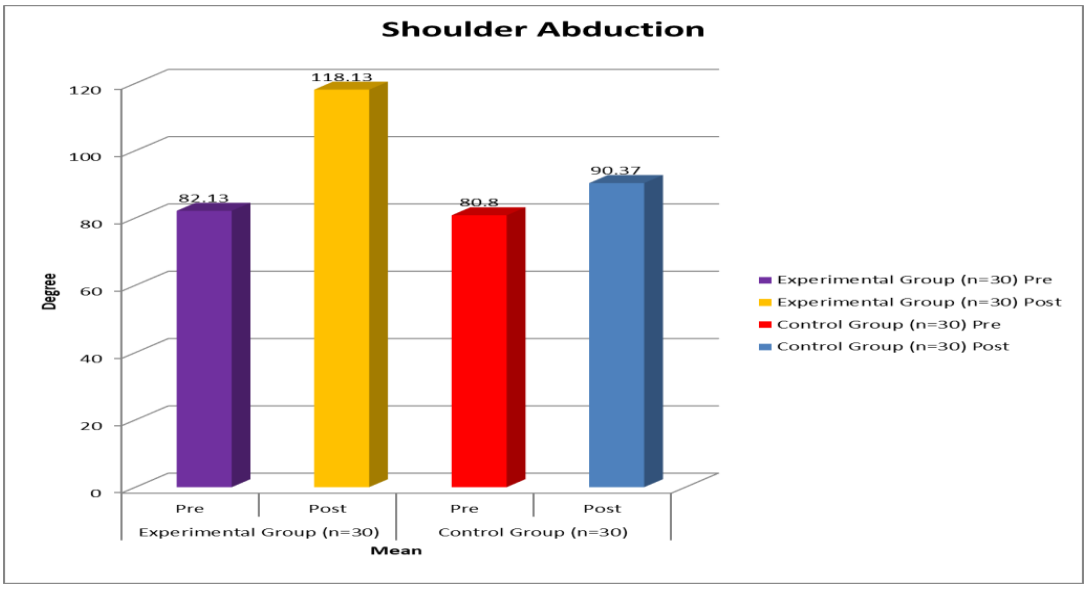


Figure 37:Comparison of ROM-Shoulder External Rotation (%) in a bar diagram.

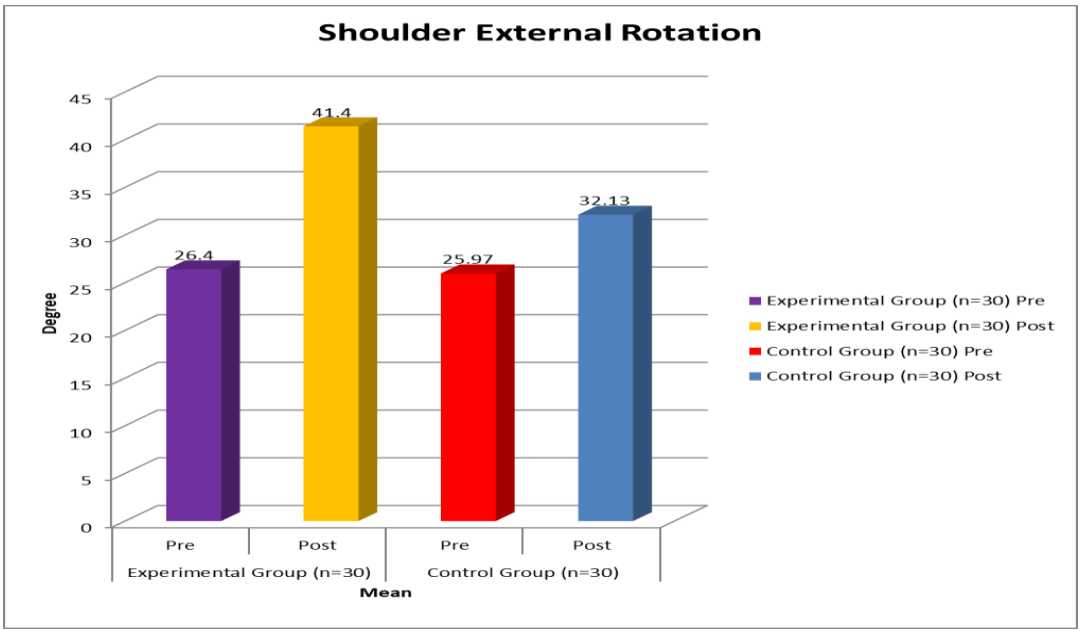
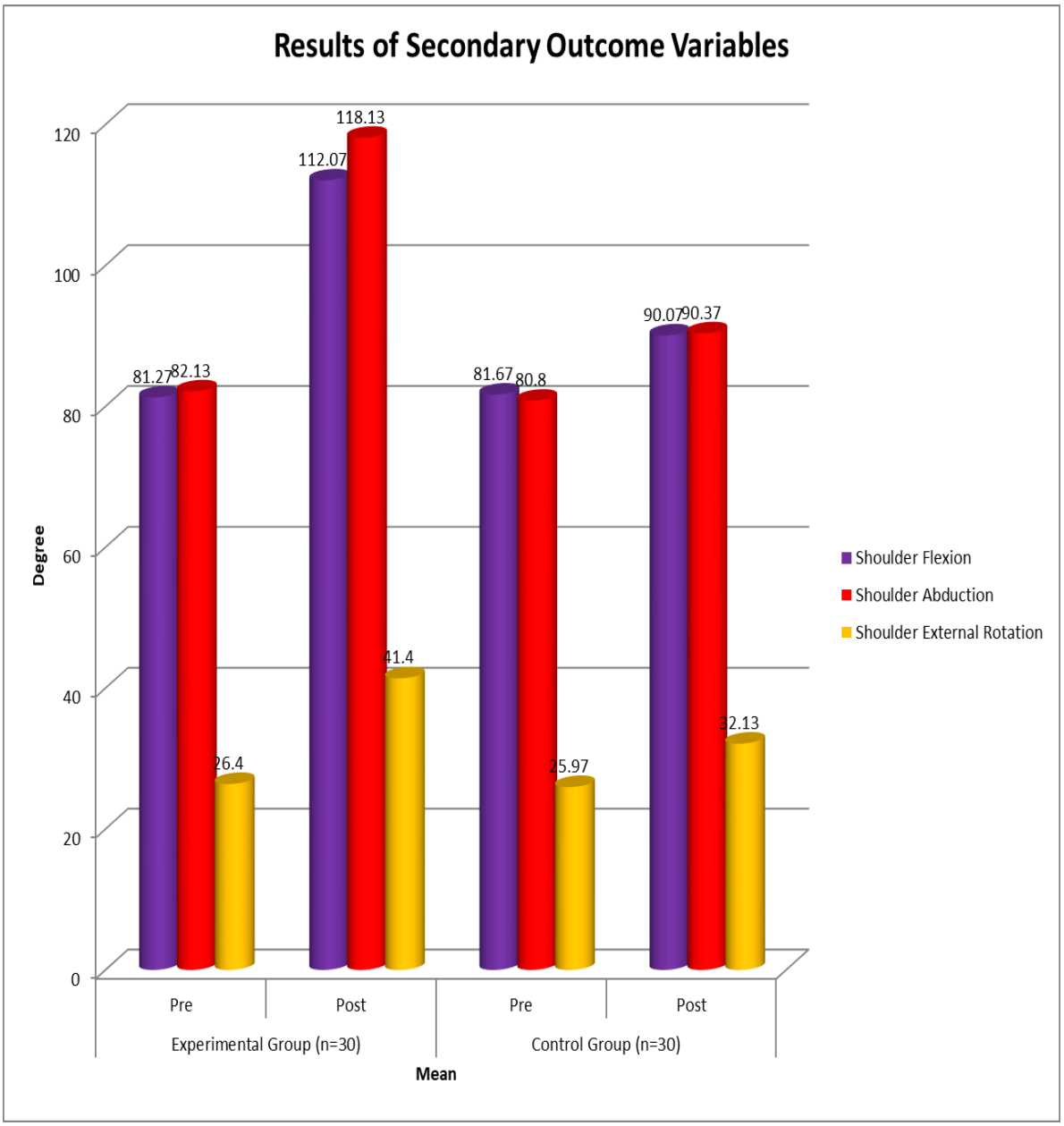


Figure 38: Results of Secondary Outcome Variables in a bar diagram



6.0 DISCUSSION

Auriculotherapy is a therapeutic technique that can be used independently as well as in a complementary way to any other treatment. This technique is often referred to as ear acupuncture or auricular acupuncture and consists of treating very precise points on the ear for therapeutic purposes.

In this study we have used Auriculo- acupuncture points as an intervention. SPADI questionnaire and ROM – flexion, abduction and external rotation are the variables used to measure the pain, disability and restriction of shoulderjoint.

The result of this study revealed Auriculoacupuncture may alleviate the symptoms of Periarthritis of shoulder in pain and disability index and also in the range of motion of flexion, abduction and external rotation. Specific points in ear such as Shoulder joint point, Shoulder point, Jerome point, Shenmen point, Thalamus point for 12 sessions.

Studies done that Auriculotherapy has better result in managing pain and musculoskeletal disorders. Systemic review of *green et al* (32) says that no adverse effect was noticed, in this study also observed that no subjects were had any adverse changes during the 12 sessions on sixty subjects. This study has no drop out. Subjects were compliance to the intervention.

Chen et al (33)in 2006 shows that both normal acupuncture and shallow needling with short needle was clinically benefited and there was no significant changes between the two groups, whereas in the present study we were noticed that Aurilotherapy was beneficial for the management of shoulder pain and disability. There was also significant changes have been observed in the experimental group.

A RCT on three phase acupuncture and routine acupuncture showed that three phase acupuncture may have therapeutic effect than the regular or local acupuncture (34).

In this study auriculo acupuncture may have high therapeutic value in both clinically and statistically. In our study shows auriculo acupuncture was effective in management of pain and disability index and range of motion of shoulder on PAS subjects.

Previous study on comparison between traditional, standard, sham acupuncture on SPADI showed that clinical improvements was noticed in the both individualized or traditional acupuncture points and standard acupuncture, our study results also showed that total SPADI score was improved in Auricultherapy.

Another multi-centric study shows that acupuncture may help to alleviate the symptoms of PAS than the conservative orthopedic treatment(35). Our study also shows that symptoms of PAS like pain, restricted movements were improved after 12 session of Auriculo acupuncture for 2 weeks.

Han z et al, in 2014 observed that combined therapy of local acupuncture, warm needling and positive functional exercise may be benefited for acute stage of PAS and combined therapy of local acupuncture and distal acupuncture with filiform and warm needling and positive functional exercise could be beneficial for chronic stages of PAS (36)**.**In our study we have included both acute (Painful) and chronic (frozen) stages of PAS. We have find that any stages of PAS could get improvement in ROM and pain by adopting auriculoacupuncture.

Taguchi et al. (2002) found that AA reduced the requirement for anesthetics (i.e. desflurane) by around 8.5% . Greif et al. (2002) found that the auriculo electric Stimulation resduced the anaesthetic requirement by 11% . Allais et al. (2011) found that when improving migraine,by using the Auriculopoints were more effective than other points which has no significance because auriculo points correspond to our body's somatotopic representation on the ear(6).

Usichenko et al. (2005, 2007) found that in 120 patients who underwent outpatient knee surgery, AA helps to reduce the consumption rate of ibuprofen . And also, in the patient receiving total hip arthroplasty, Usichenko et al. (2005) found that the administration of AA results in consumption rate of piritramide (6).

The successful effect may be due to the fact that auriculotherapy can activate meridians and collatreals regulate chi and blood, help to achieve

a balance between yin and yang states of internal organ and therfore suitable for treating many disorders of the body. It uses the theory of the five elements of the traditional chinese medicine which interacts, overacts, and counteracts among the zang fu organs together with the existence of the bi- directional regulatory mechanism of the acupoint. It is thought that the zang fu organs can put them all into a state of unity, balance and co – ordiantion.

According to this study, the selected auriculo therapy points in this study helps to alleviate pain in the PAS and also improve the range of movement.

7.0 CONCLUSION

The present study shows that Auriculotherapy improves ROM and alleviates pain measured by SPADI score for Pain and disability index, restrictions were calculated by assessing range of motion of shoulder abduction, shoulder flexion and shoulder external rotation.

Yet Auriculotherapy results statistically shows that it improves ROM especially shoulder external rotation to greater extent compared to the control group treatment regimen.

The study sample is limited and the time frame of the study is also restricted. A large cohort study with follow-up for recurrence is much needed to validate these results and it might change the current treatment options of PAS and can greatly reduce the alignments of this particular disease.

7.1.Limitations :

a) The sample size was relatively smaller.

b) Room temperature was not maintained equally to all subjects during treatment.

c) Diurnal variations might have influenced theresults.

d) Other physical activities and diet in home might acted as confounding factors for this study.

e) Mechanism of specific acupuncture points in the management of pain, disability and ROM of shoulder still in conclusive.

7.2 Directions for future research

a) This study should replicate with lager sample size.

b) A randomized controlled trial with multi arm study could be better for definite conclusion.

c) Strong methodology with follow-up is essential to support our result.

d) Objective variables like digital goniometer; bio-markers for the pain can be used.

e) Mechanism of specific acupuncture points should be evaluated in depth.

8.0 SUMMARY

The main objective of the study is to have a clear insight about the fact that PAS is major musculoskeletal disability which burdens the patient with Everyday life activity. PAS affects 2%-3% in general population and 20% of diabetic patients. PAS can cause painful and prolonged immobilization of shoulder with decreased collagen length, fibro fatty infiltration into the capsular recess, ligament atrophy resulting in decreased stress absorption, collagen band bridging across recesses, random collagen production, and altered sarcomere number in muscle tissue

Auricular acupuncture is a special acupuncture form and is often used as a complement to acupuncture in the body. It is based on a model of thought contained in itself. A key idea is the somatopy concept. This expression consists of the Greek word soma (= body) and topos (= location) and means the body's differentiated mapping in one area (here the auricula). The body's representation on the ear calls a vaguely inverted fetus to mind

In this study we have used specific auriculo acupuncture points such as shenmen, jerome point, shoulder point,shoulder joint point ,thalamus point as an intervention. SPADI questionnaire and ROM – flexion, abduction and external rotation are the variables used to measure the pain, disability and restriction of shoulder joint.

Sixty subjects were randomly assigned into experimental group (n=30) and control group (n=30). Both groups were assessed at baseline and at the end of 12 sessions for Shoulder pain and its disability index

(SPADI) and the range of motion (ROM). Intervention was six days a week for two weeks. Sterile needles were placed on the particular auriculo points for 20 min. The experimental group shows the significant changes in both statistically and clinically in pain index, disability index, total SPADI score, shoulder flexion, abduction and external rotation. Overall Auriculo acupuncture can be used as management of shoulder pain and restriction of shoulder joint with cost effective and without any side effects.

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ANNEXURE –I

INFORMED CONSENT FORM

Government Yoga and Naturopathy MedicalCollege & Hospital
Arumbakkam, Chennai-106

Participant's Name: ----------

Title of Study	THE EFFECT OF AURICULOPUNCTURE IN PATIENTS WITH PERIARTHRITIS SHOULDER-A PROSPECTIVE RANDOMIZED CONTROL STUDY
Researcher	**Dr.K.UMADEVI,** M.D in AEM Department of Acupuncture and Energy Medicine Govt. Yoga and Naturopathy medical college,Chennai.

I have been invited to participate in the research of**"The Effect of Auriculopuncture in Patients with Periarthritis Shoulder-A Prospective Randomized control Study"** I understand that it will involve the practice of puncturing with sterile needles, which may be useful for my well-being.

I have been informed that there will be pre and post assessments where non-invasive methods will be used to measure range of motion using goniometer and SPADI questionnaire.

I am aware that there may be no benefit to me personally and that I will not be compensated whatsoever.

I had given the opportunity to ask questions about the study and the questions what I asked have been answered to my satisfaction.

I understand that I have the right to withdraw from the research at any time without affecting my medical care or legal rights.

Hereby, I confirm that I have understood the above study.I myself consciously give consent to participant in this study.

Date : **Signature:** _____

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has given opportunity to ask questions. I confirm that the individual has given consent consciously.

Researcher:

Date : **Signature: _____**

ANNEXURE – II

CASE SHEET

Name: **Age:**

Sex: **OP No:**

Group & Participant No:

Chief Complaints:

History of Present Complaints:

Past History:

Provisional Diagnosis:

Variables

SPADI

Pain Scale	Pre -	Post -
Disability	Pre -	Post -

Range of Motion

Flexion of Shoulder	Pre -	Post -
Abduction	Pre -	Post -
External Rotation	Pre -	Post -

ANNEXURE – III

SHOULDER PAIN AND ITS DISABILITY INDEX (SPADI) QUESTIONNAIRE

Name: _____ **Date:** _____

Instructions:
Please answer the following questions by writing a number from 0-10 in the blank provided. If you feel a questions does not pertain to you please put a NA (not applicable) i the space. We will ask you to repeat this index in order to help our facility keep track of our treatment outcomes.

Pain scale: On a scale of 0-10, How severe is your pain: **0 = "no pain at all"----------10 = "worst pain imaginable"**	
1. At its worst?	
2. When lying on the involved side?	
3. Reaching for something on a high shelf?	
4. Touching the back of your neck?	
5. Pushing with the involved arm	
Disability scale: On a scale of 0-10, How much difficulty do you have: **0 = "no difficulty"----------10 = "so difficult it required help"**	
1. Washing your hair?	
2. Washing your back?	
3. Putting on an undershirt or pullover sweater?	
4. Putting on a shirt that buttons down the front?	
5. Putting on your pants?	
6. Placing on object on a high shelf?	
7. Carrying a heavy object of 10 pounds?	
8. Removing something form your back pocket?	

To be completed by office staff:
Circle one: Initial / Re-eval / Discharge
Diagnosis: _____Total # of treatments: ____

Pain Scale Score: _____ **Disability Scale Score:**	**Total Score: _____**

[Scoring: Summate the scores and divide by the highest score possible (130 if all questions answered). If an item is deemed not applicable, no score is calculated. Multiply the total score b 100.]

Roach KE, Budiman-Mak E, Songsirdej N, Lertratanakul Y. Development of a shoulder pain and disability index Arthritis Care Res 1991;4:143-9.
Source: Adapted from: Lewis C, Wilk, Wright R. The Orthopedic Outcomes Tool Box.
Virginia: Learn Publications.